

## COVID Vaccine VAERS Reports for Blood Clots / Thrombosis / Embolism - May 7, 2021

Notes	Vaccine Type	Vaccine Manufacturer	VAERS ID	Age	Onset Interval	Adverse Event Description
	COVID19 VACCINE	JANSEN	1156253-1	65+ years	0 days	I didn't have pain in the arm, after an hour I had a slight headache. The headache lasted about a day. After the 3-4 day I had severe diarrhea and stopped taking my supplements. It stopped for a couple days then came back for a day. I had no headache or pain, just 3 bad episodes of diarrhea. On March 24th I went into the Hospital with severe pain in my lower left back side. I thought I was passing a kidney stone, with the pain I was having. When I got there they did a CT scan and blood work and it wasn't kidney stone but I had a blood clot on the lower left side of lung and the right side as well. They immediately put me on blood thinners. I was there for a day and a night. They released and put me on medication. I've had minor pain but nothing like the pain I had before. I have since followed up with a Podiatrist and PCP. Pulmonologist said I had blood clots but couldn't give me a cause. My PCP said she thought I had or have Covid. I asked to have my blood drawn and she said it was too late for that because I had taken the vaccine already.
	COVID19 VACCINE	JANSEN	1183644-1	65+ years	0 days	Shortness of breath, hypertension, hypoxia, tachycardia, lips and fingers turn blue, high fever, rash, hives, joint pain, whole body aches, left lower leg burning, artery blockages, infection, weakness, dizziness, tunnel vision, sweating, headache, new onset atrial fibrillation with rvr All of the above symptoms first occurred 30 minutes after injection of vaccine The atrial fibrillation occurred 6 days after injection Left lower leg started burning 15 days after injection The arterial blockages and thrombus 18 days after injection by medical diagnosis due to instantaneous shut off of blood to left leg
	COVID19 VACCINE	JANSEN	1185426-1	50-59 years	0 days	lymph node swelling with pain; blot clot, blue bruise like
	COVID19 VACCINE	JANSEN	1186558-1	65+ years	0 days	Patient was transported to the hospital with c/o pain in her leg(s) and diagnosed with a DVT.
	COVID19 VACCINE	JANSEN	1191213-1	40-49 years	0 days	systemic reaction followed by deep vein thrombosis
	COVID19 VACCINE	JANSEN	1193757-1	50-59 years	0 days	Shortly after receiving the vaccination I started to experience chronic exhaustion, leg cramping and pain in my lower back right side, upper right thigh, behind my right knee and down into my right calf. I figured that the pain would go away but the pain increased and my leg started swelling and the pain increased making it very difficult for me to put my leg down on the ground and put pressure on my right leg.
	COVID19 VACCINE	JANSEN	1194975-1	30-39 years	0 days	Severe shaking. Admitted to ED for 180/90 blood pressure and rapid heartbeat (>120). Screened for potential pulmonary embolism and blood clots
	COVID19 VACCINE	JANSEN	1199724-1	30-39 years	0 days	General muscle ache Dizziness Chills Very severe headache blew out my nostrils this morning and clotted blood came out
	COVID19 VACCINE	JANSEN	1201089-1	50-59 years	0 days	Blood clotting and bleeding in lungs, severe headache, hemoptysis
	COVID19 VACCINE	JANSEN	1201760-1	60-64 years	0 days	Developed bilateral DVT with right sided PE within 2 days of vaccine. Clinically stable.
	COVID19 VACCINE	JANSEN	1202579-1	65+ years	0 days	On Saturday, 4/10/21, approximately 2 hours post vaccination, patient noted a knot on her left lower leg. No pain, redness or swelling noted to left lower leg. Patient took it easy the rest of the day. On Sunday, 4/11/21, patient began to have N/V, diarrhea and fatigue. No fever noted at this time or up to time of this report. As of 4/13/21, at 12:00pm the knot still remains present on left lower leg, along with fatigue and nausea. Patient was instructed to call PCP. Patient has an appointment with PCP on 4/14/21 at 1030am.
	COVID19 VACCINE	JANSEN	1203881-1	30-39 years	0 days	Chest pain developed 12 hours following administration. Presented to hospital on 4/13/21 diagnosed with pulmonary embolism.
	COVID19 VACCINE	JANSEN	1204097-1	40-49 years	0 days	The vaccine was administered and within a few hours the patient was noted to be tachypneic and tachycardia RR 30s-40s; HR 130s. ABG done revealing hypoxemia to 57.6, blowing of pCO2 25.6. Lactate 6.6. EKG done revealing sinus tachycardia S1Q3T3; D-dimer 3000s; CTA done revealing a large embolus in the right mainstem pulmonary artery area crossing across midline into the left main pulmonary artery compatible with a saddle embolus. New saddle pulmonary embolism with hemodynamic instability Patient started on levophed to manage hypotension. Started tPA, and transferred to the ICU.

COVID19 VACCINE	JANSSEN	1207377-1	65+ years	0 days	Patient had vaccine on 03/15/2021. Started complaining of extreme pain in RLE by that evening. Patient contacted health agency and portable x-rays came out to view RLE. No fractures were seen. Pain continued and was unmanageable by 03/20/2021 and patient was transported to the ER. Patient was found to have blood clot in RLE and admitted to ICU. Patient further declined while admitted having multiple system failure and passed away on 03/25/2021.
COVID19 VACCINE	JANSSEN	1207534-1	30-39 years	0 days	Headache blood clots dizziness on and off and reduce of appetite
COVID19 VACCINE	JANSSEN	1207733-1	60-64 years	0 days	PATIENT DEVELOPED RIGHT POPLITEAL DVT IN LEG AFTER JANSSEN/JOHNSON AND JOHNSON VACCINATION. PRESENTED TO MEDICAL GROUP 2 WEEKS AFTER VACCINATION WITH A 2 WEEK HISTORY OF LEG PAIN AND WAS DIAGNOSED AT THAT TIME. HE RECEIVED JOHNSON AND JOHNSON VACCINE AT MEDICAL CENTER.
COVID19 VACCINE	JANSSEN	1207898-1	50-59 years	0 days	Left arm and left neck/face tingling, decreased sensation with subsequent Bell's palsy like facial asymmetry on the left side, brain fog, dizziness with position changes, pressure in head when bending over behind the left eye, aching pain in left arm, fullness in the anterior lower right neck, episode of visual stars, food and drink dripping/falling out of left side of mouth, Pain in left rib cage/chest into the left back causing her to breath shallower. ER evaluation confirmed CT finding of right superficial vein thrombosis just above the sternoclavicular joint - see imaging report info.
COVID19 VACCINE	JANSSEN	1208107-1	65+ years	0 days	Patient noticed blotches on both legs approximately 6 to 7 days after vaccine was administered. On 03/30/2021, patient fell to ground, unable to get up. Patient was taken by ambulance to Hospital emergency room. Scans revealed patient had multiple blood clots and was operated on. Later in the stay, patient developed widespread hematomas in groin, stomach, rear, and both legs. Patient was released from hospital on 4/8/2021.
COVID19 VACCINE	JANSSEN	1208309-1	50-59 years	0 days	severe lethargy, shortness of breathe and fatigue (potential blood clot), went to PCP and prescribed Eliquis and Prednisone; however, written documentation said that he had no prior history of clotting prior to the vaccine.
COVID19 VACCINE	JANSSEN	1208468-1	40-49 years	0 days	DAY 1- two hours after vaccine my right arm and right leg felt restricted, numb and had some tingling in my hand, dull headache, muscle pain and dizziness. Day 2- mild pain at injection sight, muscle pain and general tirednes, dull headache,dizzy, right arm& left arm felt restricted and numbness in right pointer finger. Right leg felt restricted and pain behind the knee. Day 3- dizzy, dull headache, faint, high blood pressure, right arm & leg and left arm felt restricted and numbness/tingling in right hand. Pain behind right knee persisted. Went to ER Sunday early afternoon. Diagnosis is a cerebral venous thrombosis in sinus cavity. Still experiencing general weakness/tired, dizzy/unbalanced.
COVID19 VACCINE	JANSSEN	1213493-1	40-49 years	0 days	Had COVID on 2/7/21- Feverish feeling x 1 day, fine after. Tested negative 2/17/21. One half hour after receiving the vaccine, onset of hoarseness. Severe hoarseness persists until today. Eyelids pink, swollen slightly, persisted 2 weeks. Did not feel well. 4/15/21 -Hospital Emergency Room. Chest pain. Elevated blood pressure. COVID test positive. Disharged with azithromycin, zinc sulfate 220mg, ProAir. High blood pressure, new onset. On 4/6/21 BP 160/120 both arms. 4/7/21 Hospital ER. MRI, CT brain showed Dural Venous Thrombosis. To ICU for anti coagulation, until 4/14/21. MRV done. Now on floors, started coumadin. 9 days hospitalization so far. CT done again 4/15/
COVID19 VACCINE	JANSSEN	1214606-1	50-59 years	0 days	4 hrs after onset of severe headache and body pain in lymph nodes under arm pit breast, on top of kidneys and in stomach fatigue low fever. After 4 days of that I got a really super heavy period with cramping and blood clots in my menstrual flow. It was a horrible period, while the one after the surgery in Feb was very light. Dizzy and fatigue 10 days after shot on the April 8 I took a fall from a chair outside, and from Thrusday to the Saturday 10th I ended up in the Emergency room with a concussion and head symptoms including dizziness and nose bleeds. This was from a simple fall, and i suspect the covid shot might have caused complications after the fall with additional swelling and brusing.
COVID19 VACCINE	JANSSEN	1215454-1	65+ years	0 days	Pt had Johnsons and Johnsons vaccine Pt presented to the ER with shortness of breath and left leg pain. She had a CT and ultrasound that showed a PE.

COVID19 VACCINE	JANSEN	1215528-1	30-39 years	0 days	Patient noticed a small lump at the injection site almost immediately after vaccine given. That night patient developed 'pins & needles' down her left arm, arm/hand tremors, chills/fever (102.3), nausea, body aches, fatigue and shoulder pain. Patient took ibuprofen at 4 am on 4/9. Saturday (4/10) patient noticed a lump on her left forearm. She went to the doctor and an ultrasound was done on 4/14 which revealed a superficial venous thrombosis in the cephalic vein of the left forearm. Patient was told to start on aspirin 81mg on 4/15. Dr also measured injection site identified by patient as 1.5 cm below acromion process. Physical therapy will also be set up.
COVID19 VACCINE	JANSEN	1216052-1	30-39 years	0 days	Approximately 5 hours after the vaccine I developed a very bad headache followed by chills, sweats, congestion, chest pain, body pain, muscle pain, fatigue and fever. The muscle pain and weakness was so bad I would loose balance when walking. I then started to menstruate clots, not my normal cycle timing, which lasted about 2 days. The clots subsided but I am still bleeding today. I was in bed for 4 days with severe immune response symptoms. After those symptoms subsided the fatigue was so extreme it was hard to function.
COVID19 VACCINE	JANSEN	1217653-1	40-49 years	0 days	Patient reported to medical clinic 24 hours after COVID 19 injection (03/19/2021) with symptoms of visual hallucinations, myalgia, rigors, headache, nausea, vomiting and dehydration. At the time of arrival to the medical clinic, he had refractory nausea and vomiting after receiving Zofran earlier in the day at another clinical site. Medical treatment consisted of IV Fluid bolus with maintenance fluids, IV Phenergan for the nausea and vomiting, and IV Ketorolac for headache pain. His symptoms resolved and he started to feel better so a clinical decision was made to discharge him home in the care of a close friend. He declined any other treatment modalities or medications at the time of the discharge. The patient returned on 03/28/2021 with a right arm DVT proven on U/S. He was then started on anticoagulation therapy after specialist phone consult and will be closely followed.
COVID19 VACCINE	JANSEN	1219057-1	18-29 years	0 days	My son Fell out at work after shot was given. He had a seizure, he lay unresponsive on floor until medics were called. He noe has a blood clot in brain & has had 3 more seizures.Patient drives a fork lift & drives a truck he is nolonger able to do either.
COVID19 VACCINE	JANSEN	1220641-1	50-59 years	0 days	Per pt report: Pt started having body aches within a couple hours of vaccine, developed severe 9/10 pain over the next several days. L shoulder pain radiating to ribs and neck w/ muscle spasms, causing HA, R hip and sacral pain, flank pain radiating down R leg. Pt reports that vision in L eye is blurry, R eye vision intact, numbness to L arm and hand, able to move. Pt reports 1in x 0.5 in blood clot when blowing nose Thursday morning, small clot subsequently about 1/2 the size, smaller clots later.
COVID19 VACCINE	JANSEN	1221632-1	30-39 years	0 days	Unusual Heavy menstrual bleeding with clots starting hours after receiving shot. Headache and fatigue day after shot. Menstrual heavy bleeding continued for 6 days outside of normal cycle. Day 7 having moderate leg pains and stomach pains and occasional headaches.
COVID19 VACCINE	JANSEN	1231266-1	30-39 years	0 days	Around 5:30 pm in the evening following my vaccine I started having chills, headache, nausea, and fever of 101. Chills got worse, whole body was shaking and shivering. Nausea progressed into constant dry heaving. Head was pounding with the worst pain I have ever felt in my life, worse than natural child birth and worse than running marathons. The nausea was so bad and I could feel my fever burning and getting worse. I was about to vomit so got out of bed to go to the toilet to vomit and the whole room started spinning completely out of control. My heart was racing and I could hear it and feel it pounding rapidly through my ears. I couldn't walk and was so disoriented I crawled to the bathroom to throw up in the toilet. My husband heard me and came and picked me up off the bathroom floor and carried me to our bed. As the night progressed fever got worse, head was in almost unbearable pain, severe body aches over my whole body, heart racing and horrible nausea and dry heaving. I made it through the night. For two days after I had a headache and fever and nausea and body aches and couldn't get out of bed to care for my children. By the third and fourth day I was able to get out of bed at times and still felt fatigue, nausea, headache and body aches. Anytime I would stand up for 10 days after the vaccine it felt like I was rocking on a boat. I am almost at 2 weeks and still feel fatigue and dizziness at times. On April 15th, 9 days after my vaccination I had symptoms of a blood clot in my leg. I went to the Emergency Room and was diagnosed with a superficial blood clot of the leg as well as swelling in the vein. I am thankful to be alive!

COVID19 VACCINE	JANSEN	1232464-1	65+ years	0 days	pt says one of her toes on her left foot went completely numb. Within a couple of days she started swelling between her left big toe and the toe next to it. Her entire left foot started swelling and then her leg started swelling. She went via ambulance to ER. They did an US of her leg and found 2 blood clots in the back of her calf. She was given a RX for blood thinner. She went to 3 pharmacies and could not find it so she went home. She went home and then her right foot swelling as well. She went back via ambulance to ER. She was given blood thinner injection, and IV and took blood work. Pt was admitted where she stayed for 5 days. She was released and prescribed Eliquis. She has to take 20 mg a day for first week and then 10mg a day the following week for 3 months. She still has constant pain and her left foot continues to swell. Pt will have to have another US in 3 months.
COVID19 VACCINE	JANSEN	1232940-1	50-59 years	0 days	patient had a headache, weak arm, slept a lot more, experienced pain in arm as well, and a "funny feeling" in her chest. Patient went to the ER and said they found a blood clot."
COVID19 VACCINE	JANSEN	1233724-1	40-49 years	0 days	COVID-19 - Janssen ADR Come to ER on 4/8/2021 with chills, fever, weakness and dx with pneumonia after receiving COVID-19 vaccine 1 week ago and discharged on azithromycin. On 4/13/2021, came back to ED with worsening SOB, weakness, nausea and now with right thigh and leg pain, ground glass findings on CT thorax, positive for acute DVT on right leg and negative COVID testing. 4/14/2021 - right femoral vein thrombectomy and right external iliac vein angioplasty
COVID19 VACCINE	JANSEN	1241867-1	60-64 years	0 days	Received the vaccine approximately 12:22 PM on Saturday, April 10, 2021. At approximately 6:55 pm that same day (Saturday, April 10, 2021) my husband collapsed in our living room. I called 911 and the operator talked me through how to do chest compression CPR on my husband until the paramedics arrived. My husband was then taken by ambulance to hospital where doctor performed an emergency procedure wherein he removed the blood clot in one of my husband's stints (he has three) that he had put in in 2017. Doctor was able to eventually stabilize my husband's heart. My husband spent 5 days in the hospital as a result of this.
COVID19 VACCINE	JANSEN	1241986-1	50-59 years	0 days	I had 2 adverse reactions to the Janssen Covid-19 Vaccine EUA: AE #1) Roughly 15 minutes after receiving the vaccination, the lower half of my face went numb for approximately 3 hours. The people who administered the vaccine made me stay at the site for about an hour and a half to make sure that the reaction did not get worse. AE #2) 10 days after receiving the vaccination, the lower part of my left leg began to swell significantly. I went to the emergency room on 4/13/2021. When I was there, they did tests and confirmed that I have a blood clot behind my knee. To treat the blood clot, the emergency room doctor gave me lovenox 110mg and warfarin 5mg. Since then, I have followed up with my primary doctor who has me taking warfarin 10mg ( 1x daily) and lovenox (as needed).
COVID19 VACCINE	JANSEN	1242748-1	40-49 years	0 days	I took the vaccine at 2:10pm on 4/8/21 and 20 minutes later at 2:30pm on 4/8/21 my cycle started a whole week early, which is very abnormal for me. I am bleeding clots of blood for 5 days now with weakness and pains. My normal cycle is very regular and lasts 3 days, the first day is heavy then moderate, then light on the third day i barely need a liner. This has been heavy bleeding with sizable blood clots.
COVID19 VACCINE	JANSEN	1246983-1	50-59 years	0 days	After vaccination, at 10pm I started feeling flu like symptoms, fever chills shakes feeling miserable and this lasted 3 days straight, I also had diarrhea, nausea and vomiting. I woke up with a swollen jugular vein that ended up being a blood clot, 10 days later my arm was swollen up twice the size of my leg, the jugular was still swollen. I call the urgent care nurse they said to go to ER. I went to hospital got a CAT scan and ultrasound, I was given a shot of warfarin that was supposed to last for 12 hours. I went home and the next morning instead of going to the hospital, I went to hospital and they found 2 blood clots in brain, arm and leg and neck. I have had no history of blood clots and this all happened after the J&J vaccine. They did a procedure where they tried to put a balloon to relieve the pressure. The blood clots in the brain cannot be removed because of their location and it would be dangerous to remove and I am on blood thinners for the rest of my life. Multiple blood clots in body brain, arm and shoulder.
COVID19 VACCINE	JANSEN	1252112-1	50-59 years	0 days	Transverse sinus thrombosis in the brain with severe headaches, nausea, dizziness, and blurred vision. Patient report headaches began within a week of receiving vaccine. She reports a electrical tingling sensation on the top of her head, which began on Tuesday 4/20/2021.

COVID19 VACCINE	JANSSEN	1258288-1	18-29 years	0 days	PATIENT BROUGHT TO ED DEPARTMENT: HISTORY LIMITED TO PATIENT MENTAL STATUS CHANGES. PATIENT PRESENTS TO THE ED AFTER BEING FOUND ROLLING AROUND ON GROUND OUTSIDE OF APT. COMPLEX. SEVERAL HOURS INTO PATIENT STAY, HE BEGAN DROOLING. PATIENT HAD A RIGHT-SIDED FACIAL DROOP. CT ANGIOGRAM ORDERED WHICH SHOWED A THROMBUS IN THE LEFT MCA. VACCINATION OF JANSSEN VACCINE APPROX. 1 WEEK PRIOR TO PRESENTING PER PATIENTS MOTHER. UNKNOWN WHERE HE RECEIVED VACCINATION. PATIENT DIAGNOSED WITH ACUTE CVA
COVID19 VACCINE	JANSSEN	1262556-1	40-49 years	0 days	Clotting was present
COVID19 VACCINE	JANSSEN	1263011-1	18-29 years	0 days	Fever over 105, chills, cough, soar throat. aches and pain for 2 days. Led patient to go to the ER on monday 4/12. MD found blood clot at that point. No treatment was given patient was told to follow up with her PCP. Did not go to PCP as yet.
COVID19 VACCINE	JANSSEN	1266095-1	40-49 years	0 days	As soon as I took the vaccine shot I had an immediate headache, after taking the vaccine I took Tylenol and slept in the rest of the day. The next day I woke up and my arm was red and swollen. I was running fever, still had the headache and now blurry vision. My entire body was hurting. My left side of my body felt numb and tingling. The next two days the pain became worse. I did not really have an appetite. When I did eat I could barely hold my food down. On Wednesday morning I could barely get out of bed, I also felt extreme pain in my lower legs, stabbing pain in stomach and right lower side. I also had ringing in my ears, more in the right ear. I then notice a bruise on my left leg, that it was not originally there, and was also tender to touch. I went to the emergency room on the same day and I was admitted. I was in there for 4 days, they tested my leg and stated it was not a blood clot, although it look and felt like one. They discharge me and advise me that it was a migraine that was causing all my pain. This was on Sunday, I had a follow up with my PCP on the Friday, however to being in so much pain and shortness of breath, and arm pain I was advise to go to the ER on the Thursday and was admitted again. I was told in the ER I had a blood clot in my right arm and it was most likely from the IV from the previous visit. My blood pressure and heart rate was so high that they put me on medication. No matter the pain medication they gave me, it would not completely take the pain away. They discharge me again on Monday and after me begging them to get run any and all test, they said they found nothing. I'm still in the same amount of pain and same symptoms, still having trouble keeping my food down. The only thing that changed is my left arm is not as sore, however I still have a huge knot and its still warm to touch. I don't know what else to do that is why im contacting the CDC for help. I'm in a extreme amount of pain and pounding headaches. Please help
COVID19 VACCINE	JANSSEN	1272388-1	50-59 years	0 days	is at the er with blood clots in right leg
COVID19 VACCINE	JANSSEN	1280655-1	40-49 years	0 days	First 2 days: fever 101.5, whole left side pain, abdominal pain, headache, lower right leg pain 3rd day: low grade fever 100.5, lower right leg pain, left arm pain 4th day: lower right leg pain increased along with redness, swelling, red lines, and eventually I couldn't apply weight on my right leg. After visiting Urgent Care hospital, blood clots were found in my small veins.
COVID19 VACCINE	JANSSEN	1282407-1	60-64 years	0 days	Patient developed a PE approximately 2 weeks after injection for which she was admitted to hospital.
COVID19 VACCINE	JANSSEN	1289412-1	50-59 years	0 days	Pt developed pain in the left groin after 3 days. Patient had a venous doppler and is diagnosed with DVT of the left anterior tibial vein
COVID19 VACCINE	MODERNA	0908846-1	40-49 years	0 days	Very mild, but unexpected nose bloody nose from left nostril. Only noted when blowing nose. With 1 clot.

COVID19 VACCINE	MODERNA	0937579-1	60-64 years	0 days	On 12/31/2020, at approximately 00:15, pt developed a fever of 102.9 F and tachycardia with rate of 120. He was treated with acetaminophen. Later in the morning, he complained of nausea, generalized muscle aches, intermittent increase in confusion. At approximately 14:00, he had a fall out of bed and at that time noted to be short of breath, tachypneic. He was taken via ambulance to Emergency Department. From there he was transferred to Hospital for admission with acute respiratory distress, suspected sepsis with lactic acid 7.4 and Bilateral Pulmonary Emboli. He was started on heparin and broad spectrum antibiotics and transitioned to ELIQUIS on 1/3/2021. Infectious etiology of sepsis was unclear. He continued broad spectrum antibiotics with clinical improvement. Abdominal CT scan was obtained due to intermittent nausea, vomiting, abdominal pain, loose stools. His heart rhythm flipped to Atrial Fibrillation with RVR on 1/2 and his rate improved with titration of metoprolol. He was also treated with prednisone for suspected underlying undiagnosed COPD. It is noted in his hospital summary that PEs presumed provoked in the setting of his recent COVID 19 infection. He was discharged from the hospital on 1/8/2021 and readmitted to the Veterans Home. He has been stable.
COVID19 VACCINE	MODERNA	0946141-1	65+ years	0 days	Moderna COVID-19 Vaccine At 2 PM I went blind in my left eye. Went to emergency room at Hospital Was told I have Blood clot in my eye causing the blindness and Ophthalmologist says it will probably be permanent
COVID19 VACCINE	MODERNA	0971796-1	50-59 years	0 days	The patient became short of breath and decreased oxygen saturation at home around 2000 on 01/18/2021. He reported to the ED on 01/19/2021 at approximately 0500. The patient was found to have bilateral pulmonary emboli.
COVID19 VACCINE	MODERNA	0973105-1	Unknown	0 days	Pulmonary embolism; Blue lips; Immediately after getting shot she couldn't breathe; A spontaneous report was received from a nurse who was also a female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced difficulty breathing, blue lips, shortness of breath, and pulmonary embolism. The patient's medical history included pulmonary embolism. No relevant concomitant medications were reported. On 30 Dec 2020, moments prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot number 026L20A) intramuscularly for prophylaxis of COVID-19 infection. The patient began to feel like she couldn't breathe, and her lips were blue immediately after receiving the vaccine on 30 Dec 2020. The symptoms resolved within an hour. On 05 Jan 2021, she developed shortness of breath and experienced pulmonary embolism. Treatment included apixaban. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, difficulty breathing, blue lips, shortness of breath, and pulmonary embolism, were not reported.; Reporter's Comments: This case concerns a female patient, nurse, of unknown age with medical history of Pulmonary embolism, who experienced a serious, unexpected event of difficulty breathing, cyanosis and pulmonary embolism. The event of difficulty breathing and cyanosis occurred immediately and pulmonary embolism occurred after 7 days after first dose of mRNA-1273 (lot number 026L20A). Based on the current available information and temporal association between the use of mRNA-1273 and the start of the event, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	0981912-1	65+ years	0 days	Patient presented to the Emergency Department complaining of chest pain, pale, cool diaphoretic, and hypotensive. The patient was discovered to have a large saddle pulmonary embolism, went into cardiac arrest and expired. Of note, the patient received her second Moderna COVID vaccine on 1/23, which would place her first one approximately 12/25 if she received them at the appropriate interval. This information is from the patient's daughter and the ED record, the information is not available in CAIR. Per the daughter, the patient started feeling ill on 1/21, improved on 1/25, and then acutely worsened on 1/27, resulting in the ED visit.

COVID19 VACCINE	MODERNA	0985625-1	50-59 years	0 days	Big black thing; Big scar; Felt like chemical burn; Peeling; Cellulitis; Extravasation in tissues; Bruising from upper arm down to elbow; Arm was hot and tender; Swelling from upper arm down to elbow; Arm hot and tender; Bump/clot at injection site; Unsure if it was given intramuscularly; A spontaneous report was received from a physician who was also a 59-year-old female patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced a bump/clot at the injection site, swelling, bruising from upper arm to elbow, feeling hot, tenderness, extravasation in tissues, vaccination site cellulitis, a big blackened area, scar, chemical burn, unsure whether it was intramuscular and peeling. The patient's medical history was not provided. Concomitant medication use was not provided by the reporter. On 23 Dec 2020, immediately prior to the onset of symptoms, the patient received the first of two planned doses of mRNA-1273 (Lot number unknown) intramuscularly in the left arm for prophylaxis of COVID-19 infection. The physician reported that she was injected with the vaccine abruptly and roughly. She noticed a bump at the injection site right away. The nurse applied a cold compress. Later that day, she realized it was a clot. On 24 Dec 2020, she had swelling, bruising from her upper arm to her elbow, and the area was hot and tender. On 30 Dec 2020, she went to the emergency room where an ultrasound showed extravasation in the tissues. She was treated with cephalexin for cellulitis. On 01 Jan 2021, the bump began to subside; however, there was a large black area that started to peel. The reporter stated it looked like a chemical burn. On an undisclosed date, there was a large scar in its place. Treatment for the events included a cold compress and cephalexin. The reporter stated she is unsure whether it was intramuscular. Action taken with mRNA-1273 in response to the events was not provided. The event, scar, was not resolved. The outcome of the events, bump/clot at the injection site, swelling, bruising from upper arm to elbow, feeling hot, tenderness, extravasation in tissues, vaccination site cellulitis, a big blackened area, chemical burn, and peeling, were considered resolving. The event, unsure whether it was intramuscular, was resolved.; Reporter's Comments: This report refers to a case of incorrect route of administration for mRNA-1273 and concerns a 59 year-old, female patient, who experienced the events of bump/clot at the injection site, swelling, bruising from upper arm to elbow, feeling hot, tenderness, extravasation in tissues, vaccination site cellulitis, a big blackened area, scar, chemical burn and peeling. The event of bump/clot at the injection site occurred the same day after the first and only dose of mRNA-1273 vaccine administration. The events of swelling, bruising from upper arm to elbow, feeling hot, tenderness occurred the next day after the vaccine administration. The events of extravasation in tissues, vaccination site cellulitis occurred 7 days after the vaccine administration. The events of a big blackened area, scar, chemical burn and peeling occurred 9 days after the vaccine administration. Based on the current available information and temporal association between the use of the product and the start of the events, a causal relationship cannot be excluded and the events are assessed as possibly related.
COVID19 VACCINE	MODERNA	0988061-1	65+ years	0 days	Chills, fever, fatigue from day of onset. Currently in ICU for ARDS

COVID19 VACCINE	MODERNA	0990361-1	Unknown	0 days	blindness in left eye; stroke in back of the eye; blood clot; A spontaneous report was received from a consumer concerning an 83-year-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced blindness in left eye, blood clot, and stroke in back of the eye. The patient's medical history was not provided. Concomitant medications reported included comerdol, losartan, hydrocortisone, meloxicam, and unspecified stomach pills. On 14 Jan 2021 at 10:15 am, approximately 3 hours and 45 minutes prior to the onset of the events, the patient received a dose of mRNA-1273 (Lot number: 013L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 14 Jan 2021 around 2:00 pm, the patient lost sight in her left eye as a result of a blood clot and stroke in the back of her eye. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, blindness in left eye, blood clot, and stroke in back of eye, was unknown.; Reporter's Comments: This case concerns an 83-years-old female patient, who experienced a serious unexpected event of blindness unilateral, retinal artery occlusion, and thrombosis. The event of blindness unilateral and retinal artery occlusion occurred 3 hrs. after first dose of mRNA-1273, lot # 013L20A. The event of thrombosis occurred on an unspecified date after first dose of mRNA-1273, lot # 013L20A. Treatment included details were not provided. Concomitant medications included Comerdol, Losartan for blood pressure, Hydrocortisone, Meloxicam and stomach pills. Very limited information regarding this event has been provided at this time. Based on the current available information and temporal association between the use of the product and onset of the event a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	0993497-1	Unknown	0 days	Blood clot; Swelling at the injection site; Redness at the injection site; A spontaneous report was received from a consumer concerning a 85-year old, male patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced swelling at the injection site, redness at the injection site and blood clot. The patient's medical history was not reported. The patient current condition included chronic obstructive pulmonary disease (COPD). No relevant concomitant medications were reported. On 11 Jan 2021, approximately 0 days prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 11 Jan 2021, the patient's wife called his doctor as he was experiencing swelling and redness. They were referred to the emergency room (ER) by their doctor for a suspected infection. In the ER they were told it may be a blood clot and the patient was given prednisone. Treatment for the events included prednisone. Action taken with mRNA-1273 in response to the events was not reported. The outcomes of the events swelling at the injection site, redness at the injection site and blood clot were unknown.; Reporter's Comments: This case concerns a 85 year-old, male patient, who experienced events of swelling at the injection site, redness at the injection site and blood clot. The events occurred the same day after the first and last dose of mRNA-1273 vaccine administration. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded and the events are assessed as possibly related.
COVID19 VACCINE	MODERNA	0995419-1	30-39 years	0 days	Shortness of breath, abnormal ECGs, lack of oxygen to the heart, numbness of legs and arms, tachycardia (130-160) for over 12 hours, difficulty breathing, bilateral pin point pain in legs, dizzy, syncopal convusions, fainting, hyperventilation, vomiting, chills, headache, heart pain, fever, kidney pain
COVID19 VACCINE	MODERNA	0997677-1	65+ years	0 days	Rapid decline in health status, Elevated BP&P, posturing, loss of consciousness, Glasgow coma Scale 4 starting 2/1/2021, Deceased 2/3/21
COVID19 VACCINE	MODERNA	1034409-1	30-39 years	0 days	Very early menstruation, occurring a couple of hours after the vaccine. It started as spotting that night, (I never spot) then a gradually heavier flow, working up to an unusually heavy & painful period over the course of the next 2 days. Also some very light clotting, which rarely happens for me. I was not due for my period for 2.5 weeks. My cycle is extremely regular and has never deviated from 28-31 days in the last 6+ years. I have a copper IUD (for 6 years), and have never been pregnant.
COVID19 VACCINE	MODERNA	1047576-1	65+ years	0 days	diarrhea low gas pain chills / sweating dry mouth sleepy no apatite cough with phlegm dizzy loss of bladder control blood clots in nose mucus
COVID19 VACCINE	MODERNA	1052845-1	65+ years	0 days	Blood clot in left arm.

COVID19 VACCINE	MODERNA	1059017-1	65+ years	0 days	MODERNA COVID-19 VACCINE EUA Patient's arm was sore after injection and later that evening pain spread down to her elbow. In the following days she states that it spread to her fingers and included temporary numbness which resolved in a short period of time. Her arm remained sore with warmth and redness about the size of a quarter at the injection site. The warmth, redness and pain did not resolve so she went to the emergency room today.
COVID19 VACCINE	MODERNA	1066175-1	65+ years	0 days	pt developed a DVT and is being treated with Eliquis for 3 months
COVID19 VACCINE	MODERNA	1072810-1	65+ years	0 days	SOB and HTN on 1/30/21, 3 wks after 1st Covid shot. Submassive acute saddle pulmonary embolism. Pt was sent by ambulance to ER. On arrival, CT revealed a saddle embolism. Heparin was initiated and pt was transported to hospital. Admitted to ICU and bil thrombolytic catheters were placed. On 1/31/21 thrombosis has dissolved. on cessation of thrombolysis and removal of lytic stents on 1/31/21 pt was placed on Xarelto. Pt was D/C on 2/1/21.
COVID19 VACCINE	MODERNA	1075247-1	50-59 years	0 days	Deep vein thrombosis left calf; Difficulty breathing; Pulmonary Embolism; Felt doggy, sluggish, punky; Arm hurt; A spontaneous report was received from a nurse concerning a 54-year-old, male patient who experienced pulmonary embolism, deep vein thrombosis, vaccination site pain, sluggishness and dyspnoea. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On 12-Feb-2021, approximately 2 days prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number: unknown) intramuscularly in the left arm for prophylaxis of COVID-19 infection. The patient received his vaccine on 12-Feb-2021 and reported that his arm hurt a little for a few days. On 14-Feb-2021, he reported that he started feeling sluggish and on 20-Feb-2021 he began to have difficulty breathing and pain in the right lower base of rib cage. He went to urgent care where he was diagnosed with a pulmonary embolism for which he received treatment. On the evening of the same day, he again started having difficulty breathing with pain upon inhalation. He returned to urgent care and was subsequently admitted at 12:30 AM on 21-Feb-2021. That Monday, 22-Feb-2021, a doppler ultrasound revealed a deep vein thrombosis in the left calf. Patient was treated with heparin intravenously (IV). He was discharged 22-Feb-2021. Treatment for the event included Xarelto 20mg twice per day for two weeks and Heparin IV. Action taken with mRNA-1273 in response to the events was not provided/unknown. The outcome of the events, pulmonary embolism, deep vein thrombosis and dyspnea, was considered recovering/resolving as of discharge on 22-Feb-2021. The outcome of the events, vaccination site pain and sluggishness, were considered recovered/resolved.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1080646-1	30-39 years	0 days	- Headache: starting about 12 hours after the vaccine and continuing for 2 days - Fatigue: starting about 12 hours after the vaccine and continuing for about 2 days - Chills: starting about 16 hours after the vaccine and intensifying until 24 hours after the vaccine administration - Fever: starting about 16 hours after the vaccine and intensifying until 24 hours after the vaccine administration - Blood clots: expulsion of clots during the same period as the fever and chills. Had completed menstruation 2 weeks prior, so not related to that.
COVID19 VACCINE	MODERNA	1086033-1	65+ years	0 days	Blood clots in arm; Arm was sore; A spontaneous report was received from a healthcare professional concerning a 67-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sore arm/pain in arm and blood clot in her arm/thrombosis. The patient's medical history, as provided by the reporter included diabetes. Concomitant medications were not included. On 15 Feb 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 031M20A) in the left arm for prophylaxis of COVID-19 infection. On 15 Feb 2021, post vaccination the patient experienced sore arm and her condition got worse. She was then taken to emergency room with blood clots in her arm. Action taken with mRNA-1273 in response to the events were not reported. The outcome of the events, sore arm and blood clot in her arm, were not known.; Reporter's Comments: This case concerns a 67-year-old, female patient, who experienced thrombosis and pain in arm. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. The patient's medical history of diabetes is a risk factor. Further information has been requested.

COVID19 VACCINE	MODERNA	1086384-1	30-39 years	0 days	On the following day after receiving my first dose of the vaccination, my arm was throbbing, completely swollen, decreased ROM and skin was RED and severely tender to the touch. Took OTC Tylenol (2) po and had no signs of relief. Pain , swelling, and skin redness lasted for 3 days. On February 10th, 2021 I had a positive pregnancy test (confirmed by bloodwork and urine) which indicated I was 6-7 weeks pregnant and had a miscarriage on March 2021, after giving live births 3 prior times. The cause of the miscarriage is unknown. I also developed a blood clot on the arm that was inserted for an IV. I have no family history or personal history of needing blood thinners.
COVID19 VACCINE	MODERNA	1093817-1	18-29 years	0 days	complaint of discomfort in the right calf starting approx. 4-5 hours after the vaccination symptoms worsened the next two day with extreme pain and redness, firmness which required ER visit for evaluation
COVID19 VACCINE	MODERNA	1094625-1	65+ years	0 days	Thrombosis in popliteal vein
COVID19 VACCINE	MODERNA	1096672-1	40-49 years	0 days	About 16 hours later I had a heart attack, 20% plaque and the rest was a blood clot that acute my artery. I was in the Hospital for two days. I ended up having angioplasty and a stent. When I went home I had post heart attack issues and a sore arm for about 3 weeks.
COVID19 VACCINE	MODERNA	1096774-1	65+ years	0 days	superficial blood clots in left leg.
COVID19 VACCINE	MODERNA	1096803-1	65+ years	0 days	Pulmonary embolism, Patient began becoming short of breath shortly after receiving her first vaccine, and then became worse with her second one. She presented with syncope and was found to have multilobar embolic burden as noted above with evidence of right-sided heart strain
COVID19 VACCINE	MODERNA	1098206-1	18-29 years	0 days	Submassive pulmonary embolus
COVID19 VACCINE	MODERNA	1101157-1	65+ years	0 days	blood clot in left forearm; Sore arm; A spontaneous report was received from a consumer concerning a 78, year, old, female patient who developed a blood clot in the left forearm. The patient's medical history included hypertension, high cholesterol and hypothyroidism. On 19-JAN-2021 the patient had two stents placed in her heart. Products known to have been used by the patient, within two weeks prior to the event, included clopidogrel bisulfate (One 5 milligram AM and PM) and apixaban (One 5 milligram AM and PM) and Aspirin. On 10-FEB-2021, approximately six days prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number not provided) intramuscularly in the left arm for prophylaxis of COVID-19 infection. The patient had a sore arm for about a day after the vaccination. Six days later the left arm was red and swollen, inside forearm four inches down below the elbow it was stinging, slightly swollen, just to a soft touch she felt lumps of swelling. The patient went to the emergency room and had blood work and an ultrasound. The emergency room doctor told her that she had a blood clot in the left forearm four inches down below the elbow. The lab test done at the emergency were blood work and ultrasound. Treatment for the event included changing her current medication to one clopidogrel bisulfate 5 milligrams AM and PM and apixaban two tablets of 5 milligrams AM and PM and to discontinue the Aspirin for one week. There was no change planned to the dosing schedule of mRNA-1273 in response to the event(s) and is scheduled to get her second vaccination 10-MAR-2021. The outcome of the events were considered as unknown. Follow up: No follow up information received.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1103549-1	65+ years	0 days	Ache in back of left leg. Thought it was a muscle strain from working in yard. Did not go away so went to Clinic February 2nd, 2021. They asked me my symptoms and then sent me for a Sonogram and discovered a DVT and later a Pulmonary Embolism in my right lower lung. I am now on Eliquis.
COVID19 VACCINE	MODERNA	1105441-1	65+ years	0 days	Pt developed RUE erythema and edema. RUE US demonstrated clot in 1 of 3 brachial veins in mid-portion of RUE. Pt prescribed Eliquis x 6 weeks ( 5 mg PO BID once. 10 mg PO BID x 7 days. Then 5 mg PO BID x 5 weeks) followed by repeat RUE US.

COVID19 VACCINE	MODERNA	1107202-1	Unknown	0 days	Migraines have become more frequent and more intense to the point of were she could not function; Developed a welt at the injection site that she describes as COVID arm which was a 3-4inch raised circle underneath the injection site; Pain under lymph nodes; Developed thrombosis on her head, but it went away; A spontaneous report was received from a consumer on 04 Mar 2021 concerning a 45-years-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed thrombosis on her head, but it went away, migraines have become more frequent and more intense to the point of were she could not function, developed a welt at the injection site that she describes as COVID arm which was a 3-4inch raised circle underneath the injection site, lymph nodes pain, which she still has. The patient's medical history was not reported. Current conditions included migraine. The patinet had allergy to latex and pineapple. No relevant concomitant medications were reported On 14 Feb 2021, the patient received their first of two planned doses of mRNA-1273 (lot: not provided) intramuscularly in right arm for prophylaxis of COVID-19 infection. Since 14 Feb 2021, patient's migraines had become more frequent and more intense to the point of were she could not function. She also developed thrombosis on her head, but it went away. The patient also developed a welt at the injection site that she described as COVID arm which was a 3-4 inch raised circle underneath the injection site. She also developed pain under lymph nodes, which she still had. No treatment information was provided. Action taken with mRNA-1273 in response to the events was unknown. The event of migraines have become more frequent and more intense to the point of were she could not function and pain under lymph nodes which she still has were unresolved, the event of developed thrombosis on her head but it went away was resolved, while the outcome of the event of developed a welt at the injection site that she describes as COVID arm which was a 3-4inch raised circle underneath the injection site was unknown. The reporter did not provide an assessment for the events thrombosis on her head, but it went away, migraines have become more frequent and more intense to the point of were she could not function, developed a welt at the injection site that she describes as COVID arm which was a 3-4inch raised circle underneath the injection site, Pain under lymph nodes, which she still has.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1107682-1	65+ years	0 days	Anaphylaxis Pulmonary embolism
COVID19 VACCINE	MODERNA	1114245-1	Unknown	0 days	Pulmonary embolism in her lungs; DVT in her leg; Chest pain in her right chest; Breathing was labored; Breaking out in hives; Chills; Dull Headache; A spontaneous report was received from a consumer concerning a female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced chest pain, breathing was labored, pulmonary embolism in lungs, DVT in leg, chills, dull headache, heartbeat is up and stayed up , D-dimer levels were high and breaking out in hives, and shortness of breath. Relevant medical history included cancer involving lungs . Relevant concomitant medication was not reported. On 13 FEB 2021, the patient received their first dose of two planned dose of mRNA-1273 (lot/batch: 015M20A) intramuscularly for prophylaxis of COVID-19 infection. On 13 FEB 2021, the patient experienced chills, headache, and heart rate increased. On 27 FEB 2021, the patient experienced chest pain, dyspnea, urticaria, pulmonary embolism, deep vein thrombosis, for which she required hospitalization. Relevant laboratory investigations included increased D-dimer. Treatment for the events included Heparin and oral blood thinner. Action taken with mRNA-1273 in response to the events was unknown. On 16 FEB 2021, the outcome of the event's chills, headache was considered as resolved. At the time of this report, the outcome of the event's chest pain, dyspnoea, pulmonary embolism, deep vein thrombosis, heart rate increased, fibrin D dimer increased and urticaria were considered as unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, the events Pulmonary embolism, DVT, is Unlikely related to mRNA-1273 and a very limited information regarding these events has been provided. Further information has been requested

COVID19 VACCINE	MODERNA	1120842-1	65+ years	0 days	this is all per family, 4 to 5 days after 2nd COVID vaccine he was acting unusual and was taken to the hospital. He had a clot in his brain and underwent brain surgery. He experienced seizures after the surgery, but it was ultimately reported the surgery went well. He remained intubated and on a ventilator after surgery. He developed complications of his lungs and kidneys while on the ventilator. Ventilator was removed 3/16/2021 and he passed away that day. The hospital providers thought the clot in the brain may have been from hitting his head over a month ago. From my understanding he was A&O, independent with ADLs, and lived in his private residence prior to these complications.
COVID19 VACCINE	MODERNA	1122253-1	18-29 years	0 days	Stroke (blood clot in vein in left side of brain), occurred Wednesday March 17 at 5:15 pm. Immediately admitted to emergency room/stroke unit and given blood thinner IV and anti-seizure medicine
COVID19 VACCINE	MODERNA	1127468-1	65+ years	0 days	Severe lethargy after receiving the shot. Constant sleepiness and malaise, nausea, confusion, loss of appetite, dizziness, Blood vessels/dots formed in her eyes. Acute renal failure and eventually death on March 18, 2021.
COVID19 VACCINE	MODERNA	1127730-1	50-59 years	0 days	A stroke occurred approximately 3 hrs after receiving vaccine. He was flown by helicopter to Medical Center. He had dysphasia which did resolve by the time he was admitted into the ER. He has since had CHF and Afib and is now on anticoagulation and diuretics. He continues to have problems with CHF, SOB, weakness and is undergoing treatment as outpatient. He is now followed by Cardiology, Neurology.
COVID19 VACCINE	MODERNA	1133359-1	65+ years	0 days	SOB x 2 weeks -> presented to ER for evaluation on 3/23/2021 and found to have a PE
COVID19 VACCINE	MODERNA	1135298-1	30-39 years	0 days	blood clot; Fever; sick feeling; chills; nausea; night sweats; A spontaneous report was received from a healthcare professional concerning a 31-year-old, male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sick feeling/illness, chills, nausea, night sweats, blood clot/thrombosis, and fever/pyrexia. The patient's medical history included Cystic Fibrosis and only has half of their liver. No relevant concomitant medications were reported. On 26-JAN-2021, prior to the onset of the events the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) intramuscularly for prophylaxis of COVID-19 infection. On 26JAN2021, the patient began experiencing symptoms including sick feeling, chills, nausea, and night sweats. The patient had blood clot and fever on 21-FEB-2021. Patient was admitted into the hospital on 22-FEB-2021 and discharged on 26-FEB-2021. He received the following tests while in the hospital: MRI, Bone Density, and LABS. Treatment of the events included Eliquis. Action taken with mRNA-1273 in response to the events was not reported. On 25 Feb 2021 the outcome of event, fever was resolved. The outcome of events, sick feeling, chills, nausea, night sweats, blood clot were unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1135692-1	Unknown	0 days	Pneumonia; Thrombus; Incoherent; dehydrated; threw up; Fever; A Spontaneous report was received from Consumer concerning 73-year-old of male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and fever, incoherent, threw up, dehydrated, blood clot and he was diagnosed with Pneumonia. The patients relevant medical history included. The concomitant medication was not reported. On 28 Jan 2021, prior to the onset of the event, the patient received their first dose mRNA-1273 (Lot number: 012M20A, Expiration date: not provided) via unknown route in the left arm for prophylaxis of COVID-19 infection. On same day, after vaccination patient experienced fever, incoherent, threw up, dehydrated. Few days later he went to the hospital because of shortness of breath, the hospital diagnosed him with a blood clot (on 31 Jan 2021), Then on 09 Feb 2021, he went to see his family doctor because he still did not feel well and he was diagnosed with Pneumonia. Treatment was included as Eliquis and Antibiotic. Action taken with the mRNA-1273 in response to the events was not provided. On 29 Jan 2021 the outcome were recovered for fever, incoherent, threw up, dehydrated. The outcome were unknown for pneumonia and shortness of breath. On 01 Feb 2021 the outcome blood clot was recovered.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events of pyrexia, vomiting, dehydration, incoherent and thrombosis, a causal relationship cannot be excluded. Based on the current available information and the mechanism of action of mRNA-1237 vaccine, the event of pneumonia is assessed as unlikely related. Further information has been requested.

COVID19 VACCINE	MODERNA	1144946-1	40-49 years	0 days	patient received dose #2, then had a total of 5 ED visits for dyspnea and other symptoms including overnight admission. patient with bilateral, sub segmental pulmonary emboli. no prior history of PE, is a long distance runner. received at outreach clinic due to being a teacher
COVID19 VACCINE	MODERNA	1148710-1	50-59 years	0 days	blood clot in lower leg; achy; Pain in the back of leg that would not go away; body ache/ache; headache; A spontaneous report was received from a consumer concerning a patient age ,57 years old male patient who developed Blood clot in lower leg/Thrombosis, Body ache/Myalgia, Headache/Headache and pain in the back of the leg that would not go away/pain in extremity. The patient's medical history included Central Retinal vein occlusion (CRVO). Concomitant product use was not provided/unknown by the reporter. The patient received their first of two planned doses of mRNA-1273 (Batch number not provided) on unknown date. The patient received their second of two planned doses of mRNA-1273 (Batch number not provided) on 03 Feb 2021, intramuscularly in the (unknown injection site) for prophylaxis of COVID-19 infection. On the same day as receiving the vaccine 03 Feb 2021 patient reported as having pain in back of the leg that would not go away. Patient also had body aches, felt achy and had headache. Patient went to Emergency room on 03 Feb 2021 and was diagnosed a blood clot in lower leg. The event blood clot in lower leg was assessed as medically significant based on IME list. Treatment information was not provided/unknown. Patient is following up with a hematologist. The patient received both scheduled doses of mRNA-1273 prior to the event(s); therefore, action taken with the drug in response to the event(s) is not applicable. The outcome of the event(s), Blood clot in lower leg/Thrombosis, Body ache/Myalgia, Headache/Headache and pain the was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events (pain, myalgia, and headache) a causal relationship cannot be excluded. A very limited information regarding these event (Thrombosis) has been provided at this time. Noting the history of central retinal vein occlusion may remain as a risk factor for thrombosis. Further information has been requested.
COVID19 VACCINE	MODERNA	1170763-1	18-29 years	0 days	Pulmonary embolism; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Pulmonary embolism) in a 25-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 027A21A) for COVID-19 vaccination. The patient's past medical history included No adverse event (No reported medical history). On 16-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Mar-2021, the patient experienced PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 21-Mar-2021 to 24-Mar-2021 due to PULMONARY EMBOLISM. At the time of the report, PULMONARY EMBOLISM (Pulmonary embolism) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported. Treatment information included was blood thinner. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1176927-1	65+ years	0 days	DVT in R leg

COVID19 VACCINE	MODERNA	1178258-1	Unknown	0 days	Blood clot in Left Arm; itchy rash from elbow to shoulder; lump on the underside of her biceps; nauseous; couldn't lift arm up; arm sore at the injection site; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clot in Left Arm) in a 63-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history.). Concomitant products included CLONAZEPAM for Anxiety, STEROIDS for Back disorder, CITALOPRAM and MORPHINE SULFATE for an unknown indication. On 23-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Mar-2021, the patient experienced VACCINATION SITE PAIN (arm sore at the injection site). On 24-Mar-2021, the patient experienced MOVEMENT DISORDER (couldn't lift arm up). On 25-Mar-2021, the patient experienced RASH PRURITIC (itchy rash from elbow to shoulder), MASS (lump on the underside of her biceps) and NAUSEA (nauseous). On 27-Mar-2021, the patient experienced THROMBOSIS (Blood clot in Left Arm) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Blood clot in Left Arm), RASH PRURITIC (itchy rash from elbow to shoulder), MASS (lump on the underside of her biceps), MOVEMENT DISORDER (couldn't lift arm up), NAUSEA (nauseous) and VACCINATION SITE PAIN (arm sore at the injection site) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment included Benadryl for symptoms and Eliquis for blood clot.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1186830-1	60-64 years	0 days	Patient reported to the pharmacy that she was admitted to the hospital for blood clots shortly after receiving the vaccination and was there for at least 10 days
COVID19 VACCINE	MODERNA	1194141-1	40-49 years	0 days	very much like a blood clot; R leg swelling; very hematoma; big red patch; warm sensation in the the leg; pain that he never had; normal pain in the injection site; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (very much like a blood clot) in a 49-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 01-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 01-Apr-2021, the patient experienced VACCINATION SITE PAIN (normal pain in the injection site). On 04-Apr-2021, the patient experienced THROMBOSIS (very much like a blood clot) (seriousness criterion medically significant), PERIPHERAL SWELLING (R leg swelling), HAEMATOMA (very hematoma), ERYTHEMA (big red patch), FEELING HOT (warm sensation in the the leg) and PAIN IN EXTREMITY (pain that he never had). At the time of the report, THROMBOSIS (very much like a blood clot), PERIPHERAL SWELLING (R leg swelling), HAEMATOMA (very hematoma), ERYTHEMA (big red patch), FEELING HOT (warm sensation in the the leg), PAIN IN EXTREMITY (pain that he never had) and VACCINATION SITE PAIN (normal pain in the injection site) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown Route) was unknown.; Sender's Comments: Very limited information regarding these events has been provided at this time. The events are probably related to the patient's comorbidities
COVID19 VACCINE	MODERNA	1197333-1	50-59 years	0 days	PATIENT WAS IN GOOD HEALTH WHEN VACCINATED ON 2-27-21. BY 3-3-21, PATIENT REPORTED TO ER WITH SHORTNESS OF BREATH AND SEVERE FATIGUE. PATIENT WAS ADMITTED TO HOSPITAL WITH DEHYDRATION AND POSSIBLE PNEUMONIA. ONCE ADMITTED, SEVERAL BLOOD CLOTS WERE FOUND IN PATIENT'S LUNG. PATIENT SPENT 4 DAYS IN HOSPITAL AND WAS THEN DISCHARGED. SHE IS SINCE IN GOOD HEALTH.
COVID19 VACCINE	MODERNA	1197919-1	65+ years	0 days	profound Lethargy, difficulty ambulating and progression to DVT bilaterally(03/27/2021)
COVID19 VACCINE	MODERNA	1203758-1	40-49 years	0 days	Patient was seen in hospital after receiving 2nd Moderna vaccine at 8am on 1/21/2021. He developed left sided chest pain a few hours earlier. Presented to hospital next day with multiple bilateral pulmonary emboli
COVID19 VACCINE	MODERNA	1204971-1	65+ years	0 days	Blood clot in large intestines which caused loss of blood supply and oxygen so it rotted which in turn rotted her small intestine and bowels which all had to be removed shut down her kidneys and liver
COVID19 VACCINE	MODERNA	1205392-1	60-64 years	0 days	blood clots in left leg and both lungs diagnosed on 2/22, died 2/24

COVID19 VACCINE	MODERNA	1209252-1	65+ years	0 days	On 4/13 patient's daughter in law called public health department to report that patient was found by EMS on 3/12/21. They believe patient had passed away over night. No autopsy was done. Family member reported that EMS believed the cause to be heart attack or pulmonary embolism.
COVID19 VACCINE	MODERNA	1213227-1	30-39 years	0 days	mesenteric venous thrombosis, symptoms began around same time as vaccine
COVID19 VACCINE	MODERNA	1217269-1	65+ years	0 days	Both my mother and father had their shots on the same day. Mother (77) had mild fatigue the day after the shot with some arm soreness. She was fine after about a day. My father reported arm soreness and fatigue that lasted about three days after the shot. He thought he was rebounding from the shot and continued his usual activities. Though, he started complaining of being ""winded"" and difficulty breathing. He slept a lot and continued with fatigue and shallow breathing. A week after his shot he felt he needed to go to the ER because of difficulty breathing and being exhausted after walking up a flight of stairs (we live in a raised ranch style house).""
COVID19 VACCINE	MODERNA	1219055-1	65+ years	0 days	On April 3, 2021 the patient received the first dose of the Moderna COVID vaccine. The patient's husband states that ""crashed an hour and a half after she got the shot."" He defines this ""crash"" as decreased blood sugar, decreased responsiveness, and the seizures. She presented to the Hospital for evaluation and was subsequently transferred to the Medical Center on April 4th for further workup. She was intubated on April 4th and subsequently self-extubated on April 8th. Nursing staff and documentation indicate that the patient has had no further seizures since her presentation to the medical center. On April 14th she was found to have an acute lower extremity DVT. She was placed on a heparin drip and her platelet's dropped to 35. The heparin drip was discontinued, a HIT panel was ordered, and argatroban was started. Heamtology was consulted and the patient was found to have thrombotic thrombocytopenia. An MRI of the brain was ordered to rule out CNS thrombosis given recent seizures. The MRI has not been performed yet and the patient is still hospitalized.""
COVID19 VACCINE	MODERNA	1219681-1	50-59 years	0 days	Admitted with acute saddle PE with RV strain on 4/13/21, syncope, required TPA. LLE with acute DVT
COVID19 VACCINE	MODERNA	1220961-1	50-59 years	0 days	Thrombosis on left arm and chest; ""you can see all of the veins""; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Thrombosis on left arm and chest) in a 56-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 037B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Neuralgia. On 08-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 08-Apr-2021, the patient experienced THROMBOSIS (Thrombosis on left arm and chest) (seriousness criterion medically significant) and VASODILATATION (""you can see all of the veins""). At the time of the report, THROMBOSIS (Thrombosis on left arm and chest) and VASODILATATION (""you can see all of the veins"" had not resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Concomitant product include an unspecified neuralgia medication. No treatment information was reported. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested.""

COVID19 VACCINE	MODERNA	1220994-1	Unknown	0 days	<p>tested positive for COVID- 19; Trouble breathing; blood clots in lungs; Chills; fever; body aches; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (blood clots in lungs) and COVID-19 (tested positive for COVID- 19) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 038A21A) for COVID-19 vaccination. The patient's past medical history included No adverse event (No medical history reported). On 16-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Mar-2021, the patient experienced THROMBOSIS (blood clots in lungs) (seriousness criteria hospitalization prolonged and medically significant) and COVID-19 (tested positive for COVID- 19) (seriousness criterion hospitalization prolonged). At the time of the report, THROMBOSIS (blood clots in lungs) and COVID-19 (tested positive for COVID- 19) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No treatment information was provided. Based on the current available information which includes a strong temporal association between the use of the product and onset of the reported events, and excluding other etiologies, a causal relationship cannot be excluded. Fever, chills and myalgua are consistent with the product known safety profile. Reporter did not allow further contact; Sender's Comments: Based on the current available information which includes a strong temporal association between the use of the product and onset of the reported events, and excluding other etiologies, a causal relationship cannot be excluded. Fever, chills and myalgua are consistent with the product known safety profile.</p>
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COVID19 VACCINE	MODERNA	1221012-1	65+ years	0 days	<p>small intestine got blocked and due to blockage blood supply stopped; started having blood clot thrombosis both in his right leg as well as left leg; Missed the 2nd dose; Blocked small intestine; This spontaneous case was reported by a nurse and describes the occurrence of SMALL INTESTINAL OBSTRUCTION (Blocked small intestine), INTESTINAL ISCHAEMIA (small intestine got blocked and due to blockage blood supply stopped) and THROMBOSIS (started having blood clot thrombosis both in his right leg as well as left leg) in a 73-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 030M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse effect (No relevant medical history reported) and Surgery. Concomitant products included thyroid medication for an unknown indication, cholesterol medication. On 13-Feb-2021 at 10:30 AM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Feb-2021, the patient experienced SMALL INTESTINAL OBSTRUCTION (Blocked small intestine) (seriousness criterion medically significant). On 13-Mar-2021, the patient experienced INTESTINAL ISCHAEMIA (small intestine got blocked and due to blockage blood supply stopped) (seriousness criterion medically significant), THROMBOSIS (started having blood clot thrombosis both in his right leg as well as left leg) (seriousness criterion medically significant) and PRODUCT DOSE OMISSION ISSUE (Missed the 2nd dose). On 13-Mar-2021, PRODUCT DOSE OMISSION ISSUE (Missed the 2nd dose) had resolved. At the time of the report, SMALL INTESTINAL OBSTRUCTION (Blocked small intestine), INTESTINAL ISCHAEMIA (small intestine got blocked and due to blockage blood supply stopped) and THROMBOSIS (started having blood clot thrombosis both in his right leg as well as left leg) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications included thyroid medication and cholesterol medication. Patient called in to report that he received his 1st dose of Moderna vaccine on 13Feb2021 in left arm at 10.30 am and his 2nd dose of Moderna vaccine was scheduled on 13Mar2021. On 13Mar2021he went to Emergency Room (ER) and he had major surgery on small intestine, patient mentioned that his small intestine got blocked and due to blockage the blood supply was stopped and the intestine started to die. On that day, the patient underwent a surgical procedure which the doctor had to take out 12 inches of small intestine and stapled back. He was hospitalized for five days. Five to seven days after his surgery, he developed blood clot thrombosis in his right and left legs. Treatment for the event included blood thinner, which he has been on for 45 days. It was reported that the second dose of Moderna vaccine was missed due to hospitalization for the events and the blood thinner that he was on. Most recent FOLLOW-UP information incorporated above includes: On 13-Apr-2021: reporter added, product indication added, event added(missed dose), event assessment done, additional info added( Source Document and mail document added); Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p>
COVID19 VACCINE	MODERNA	1221061-1	Unknown	0 days	<p>DBD blood clot in leg; Arm got little sore; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (DBD blood clot in leg) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history was reported.). Concomitant products included RIVAROXABAN (XARELTO) for an unknown indication. On 14-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 14-Mar-2021, the patient experienced PAIN IN EXTREMITY (Arm got little sore). On 05-Apr-2021, the patient experienced THROMBOSIS (DBD blood clot in leg) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (DBD blood clot in leg) outcome was unknown and PAIN IN EXTREMITY (Arm got little sore) had resolved. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Reportedly, the patient's sore arm went away pretty fast. The patient received treatment with Xarelto (Rivaroxaban) for blood clot in his leg. Company Comment Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Reporter did not allow further contact</p>

COVID19 VACCINE	MODERNA	1221137-1	65+ years	0 days	My my grandma got them a derma vaccine on January 22 she died on February 11 she was admitted to the hospital with a blood clot in her leg they tried to do surgery but when they put her under the anesthesia she never woke back up. She was 93 years old and had many other health conditions but when I called the doctors office to ask them if they reported my grandma they just kept giving me the runaround I tried to call hospital as well and I got the same thing they told me to go back to the doctor. I think someone should know and I think it?s way too difficult for family members to try to report adverse side effects it took me all day to find someone that could help me get to this website. I think there may be a lot more adverse side effects but people don?t know how to report them.
COVID19 VACCINE	MODERNA	1227470-1	65+ years	0 days	My uncle started feeling unwell the evening he got his 2nd Covid 19 vaccine. By the next evening, he started vomiting violently, trembling and sweating. He lived in country and his caregiver didn't think to take him to the hospital. The symptoms calmed down after a while, but he was not able to hold any food or liquids down. Eventually, he fell asleep and his caregiver left for the night. He returned on Easter Sunday at 9:30 am and found my uncle deceased.
COVID19 VACCINE	MODERNA	1235544-1	50-59 years	0 days	Acute pulmonary embolism/two blood clots in lung; Chest pain; Pain over left arm; pain all over joints; Nausea; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Acute pulmonary embolism/two blood clots in lung) in a 57-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 038A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history was provided). On 02-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Apr-2021, the patient experienced PAIN IN EXTREMITY (Pain over left arm), ARTHRALGIA (pain all over joints) and NAUSEA (Nausea). On 12-Apr-2021, the patient experienced CHEST PAIN (Chest pain). On 13-Apr-2021, the patient experienced PULMONARY EMBOLISM (Acute pulmonary embolism/two blood clots in lung) (seriousness criterion medically significant). At the time of the report, PULMONARY EMBOLISM (Acute pulmonary embolism/two blood clots in lung), CHEST PAIN (Chest pain), PAIN IN EXTREMITY (Pain over left arm), ARTHRALGIA (pain all over joints) and NAUSEA (Nausea) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 13-Apr-2021, Computerised tomogram: abnormal (abnormal) diagnosed acute pulmonary embolism.. Two blood clots in lung. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported. Description: The patient experienced pain over left arm, pain all over joints, nausea after vaccine administration. On 12 Apr2 021, the patient experienced chest pain and went to Emergency. Room where blood test and D-dimer was done. The treatment information included apixaban. Company Comment: Based on the current available information and the temporal association between the product use and the start date of the events a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and the temporal association between the product use and the start date of the events a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1235625-1	18-29 years	0 days	Consistent headache - Tylenol or Excedrine relieved Heavy period - began 4 days early. Excessive blood clots and amount of blood. Left arm pain- unable to move arm without pain x 3 days. Tylenol relieved Fever- began 2 days after. Tylenol reduces fever.

COVID19 VACCINE	MODERNA	1235690-1	40-49 years	0 days	Blood clots; Kind of bleeding; arm began being extremely itchy; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clots) and HAEMORRHAGE (Kind of bleeding) in a 40-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 02-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Apr-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced PRURITUS (arm began being extremely itchy). On 05-Apr-2021, the patient experienced THROMBOSIS (Blood clots) (seriousness criterion medically significant) and HAEMORRHAGE (Kind of bleeding) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Blood clots) and HAEMORRHAGE (Kind of bleeding) outcome was unknown and PRURITUS (arm began being extremely itchy) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In April 2021, Pregnancy test: Negative. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant product use was not provided by the reporter. Treatment information was not provided. Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, excluding other etiologies causal relationship cannot be excluded; Sender's Comments: Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, excluding other etiologies causal relationship cannot be excluded
COVID19 VACCINE	MODERNA	1290770-1	Unknown	0 days	Blood clot; Couldn't breathe; Heart palpitations; Hives; vertigo; This spontaneous case was reported by a health care professional and describes the occurrence of THROMBOSIS (Blood clot) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Medical History not reported. On 15-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Mar-2021, the patient experienced THROMBOSIS (Blood clot) (seriousness criterion medically significant), DYSPNOEA (Couldn't breathe), PALPITATIONS (Heart palpitations), URTICARIA (Hives) and VERTIGO (vertigo). At the time of the report, THROMBOSIS (Blood clot), DYSPNOEA (Couldn't breathe), PALPITATIONS (Heart palpitations), URTICARIA (Hives) and VERTIGO (vertigo) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. On 15 Mar 2021, within 1 hour of receiving first dose of the Moderna COVID-19 vaccine, the patient couldn't breathe, she had heart palpitations, hives, vertigo, and a blood clot. The patient stated that she was able to feel the blood clot. At the time of the report it was unclear if the patient had seen a physician for the events. Treatment for the event was cetirizine, and the patient stated that she has no hives when she takes cetirizine, but once she stops the cetirizine the hives return. Treatment provided with cetirizine for hives.
COVID19 VACCINE	PFIZER\BIONTECH	0919000-1	40-49 years	0 days	I had itching and redness and knots that formed in my left leg. The knots were at the site of a varicose vein. I sought tx at an ER on 12/26 to ensure it was not a blood clot. I followed up with my family dr on 1/4/2021 (When her office reopened) and was diagnosed with Superficial Thrombophlebitis. The knots remain in my leg. The redness has mostly gone away. My PCP felt as I recently had covid, the vaccine likely flared up the inflammation in my body and caused this condition.
COVID19 VACCINE	PFIZER\BIONTECH	0925039-1	50-59 years	0 days	SOB started Saturday 01/02/2021 continued SOB Sunday 01/03/2021 and on Monday 01/04/2021 went to clinic and saw a provider. Resulted in bilateral pulmonary emboli treated with Lovenox and Coumadin.
COVID19 VACCINE	PFIZER\BIONTECH	0926290-1	18-29 years	0 days	Presented to ED 1/3/2021 Tachycardia, fever, headache and myalgia. Complaints of shortness of breath.
COVID19 VACCINE	PFIZER\BIONTECH	0946743-1	60-64 years	0 days	She said she received her First Covid vaccine on 12/22/2020. She said on 1/4/2021 she worked that evening and started having severe pain in calf of her left leg no redness ,no heat, just hurt to work 1/8/2021 She had surgery on her left leg. 2nd Covid Vaccine received on 1/12/2021 She said she had PT on her right leg with severe pain in her left calf She said she did not have any therapy on her left leg. Two ? three hours later she developed chills, temp 100.1 took temp again later is was 99. She had ultrasound that showed a large blood clot She said the PA told her the blood clot could be from receiving the Covid vaccine

COVID19 VACCINE	PFIZER\BIONTECH	0950996-1	50-59 years	0 days	Constant headache began approximately 1 hr after receiving vaccine. Awoke this morning with blood clots on my tongue
COVID19 VACCINE	PFIZER\BIONTECH	0959470-1	65+ years	0 days	Patient seated in observation area after vaccination at 1412. At 1422 patient reported feeling heaviness in chest rated at 7/10 pain scale, mandibular pain, appeared diaphoretic and fatigued, skin grey/pale, though remained alert and responsive to questions appropriately. Patient also communicates she was having some chest pain prior to the immunization today, though she indicated on her forms that she was feeling well today. Vital signs assessed, P72 R16 O2 99, patient denied difficulty breathing. Rapid response protocol initiated, applied 2L O2 via NC, transferred patient to wheelchair and taken to ED for evaluation by response team. ED assessment reveals calf tenderness and patient reporting TKA x 2 weeks ago, elevated D-Dimer, CT results pending at this time.
COVID19 VACCINE	PFIZER\BIONTECH	0966606-1	18-29 years	0 days	Heart rate elevated to 150 and above, shortness of breath. Went to emergency room. Admitted with blood clot in lung. Previously had COVID in 2020, and we are unsure if this is related to previous illness.
COVID19 VACCINE	PFIZER\BIONTECH	0988684-1	65+ years	0 days	Patient had fall x 2 with or without syncope (conflicting documentation) with humeral fracture after receiving the vaccine. Workup demonstrated PE and DVT (appears PE was not submassive/massive, unlikely it directly precipitated fall/ syncope)
COVID19 VACCINE	PFIZER\BIONTECH	1008450-1	40-49 years	0 days	Developed DVT in left leg from groin to ankle. Diagnosed on 01/29/2021. Pain, swelling, and difficulty walking lead to emergency room visit, admission to hospital for 2 days.
COVID19 VACCINE	PFIZER\BIONTECH	1013313-1	50-59 years	0 days	Thrombosis in right axilla at superficial tributary. No Pulmonary embolism. Axilla pain developed within 48 hours of vaccine. 1 week later she noted a lump at axilla. Presented to clinic for evaluation on 2/8/21
COVID19 VACCINE	PFIZER\BIONTECH	1020708-1	18-29 years	0 days	Patient developed rapid onset of dyspnea, light headedness and tachycardia. Was taken to the ED where she was treated with an antihistamine and IV fluids. Symptoms resolved. 6 days after the vaccine, was having shortness of breath and left arm pain (not the arm where injection was received) and was diagnosed with a pulmonary embolism.
COVID19 VACCINE	PFIZER\BIONTECH	1032994-1	65+ years	0 days	Received 1st. Pfizer vaccine shot at 10:00 am Thursday 2/10/2021 At approximately 6:00 pm same day I started to have severe pain in my side shortness of breath and could not lie down to go to sleep. Had to go to bed sitting up with three pillows on my back. The next morning went to doctor who ordered blood test and chest X-Ray. Chest X-Ray indicated Pulmonary Embolism. Doctor started me on Eliquis blood thinner to hopefully dissolve the blood clot on my lung. Doctor suggested I report Pulmonary Embolism occurring same day as my first vaccine shot. Do not know if shot caused Pulmonary Embolism or just a coincidence. In addition doctor found blood in my urine and a CT of Bladder has been ordered
COVID19 VACCINE	PFIZER\BIONTECH	1052242-1	65+ years	0 days	Patient reported as being altered, GCS 6 with noted aphasia around 1415.

COVID19 VACCINE	PFIZER\BIONTECH	1058169-1	65+ years	0 days	<p>Diagnosed with May-thurner syndrome; Deep vein thrombosis; Both of her feet were only slightly swollen; Dull minor headache; Off-label use; Inappropriate schedule of vaccine administered; Localized discomfort where injection of second dose of Pfizer COVID-19 Vaccine was given; This is a spontaneous report from a contactable consumer (patient). A 65-year-old female patient (weight: 77.56 kg, height: 157 cm) received the second dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine) at single dose, in the upper left arm, on 23Jan2021, for COVID-19 immunisation. Relevant medical history included thyroid condition from an unspecified date (over 25-30 years before this report) and ongoing, controlled with levothyroxine sodium (SYNTHROID); and breast cancer from an unspecified date, in 2019 (treatment and surgery on an unspecified date, in 2019. Presumed resolved with radiation treatment, but no treatment within a year prior to getting Pfizer COVID-19 vaccine). The patient previously, on 05Jan2021 (18 days before the second dose), received the first dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine) for COVID-19 immunisation. After the first dose, the patient experienced localized discomfort at the injection site and swelling of feet. Concomitant medication included levothyroxine sodium (SYNTHROID) from an unspecified date and ongoing, 0.88 mg, daily, for thyroid condition. On 23Jan2021, the patient experienced injection site discomfort described as ""localized discomfort where injection of second dose of Pfizer COVID-19 Vaccine was given"". On 24Jan2021, she had dull minor headache. On an unspecified date, the patient was hospitalized after the second dose and was diagnosed with May-thurner syndrome. She clarified that May-Thurner syndrome was where the iliac artery collapses and crushed the iliac vein in the upper abdomen; from that point down it started creating a blood clot. She developed a deep vein thrombosis (DVT) from her left ankle up to her right rib cage area; it was a monster. On 10Feb2021, the patient experienced deep vein thrombosis and thrombectomy was performed on the same day (outpatient thrombectomy surgery, performed 10Feb2021. It was a great surgery, very corrective. She never did have any pain or discomfort which confused everyone. She felt fine this whole time, no issues). On an unspecified date, both of her feet were only slightly swollen. Relevant laboratory test, performed on an unspecified date, in 2021, included computerised tomogram (CT scan with contrast of her abdomen and chest) that showed deep vein thrombosis: left ankle-right ribcage area. The adverse events May-Thurner syndrome and deep vein thrombosis were assessed as serious, hospitalization required from 02Feb2021 to 10Feb2021. The patient recovered from deep vein thrombosis on 10Feb2021, recovered from headache on 26Jan2021, recovered from swelling of feet and vaccination site discomfort on an unspecified date, while clinical outcome of the other events was unknown. Her vascular surgeon said he did not believe these events were vaccine related but cannot rule it out; her Primary Care Physician absolutely believed the events were vaccine related. The information on the lot number has been requested.""</p>
COVID19 VACCINE	PFIZER\BIONTECH	1062452-1	40-49 years	0 days	<p>Pt presented to ED 45 minutes after receiving 1st dose Pfizer COVID vaccine with elevated BP, itching, rash and hives. Pt PE upon arrival stated that she was in acute distress. Itching,rash,hives,swelling and redness present on pt's back, chest and left arm. Progression: worsening. Moderate severity. Pt had taken lisinopril 10 mg with no improvement. Pt was treated with steroids, H1 and H2 blockers with good response. 02.01.2021 Pt presented to ED with BP of 200/140. Pt reports BP has been elevated since receiving her COVID vaccine on 01.29.2021. Pt exam positive for tinnitis. BP @ 1253 144/98, 1152 170/107, 1130 185/112, 1126 190/124. Pt BP came down with self administered hydralazine. 02.04.21 Pt presents to Ed with elevated BP of 161/111 and chest pressure. Pt has not had relief with dose of clonidine and hydralazine. She also took a dose of steroid. Pt ROS pos for chest tightness, chest pain and leg swelling. BP improved with anxiolysis.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1063404-1	50-59 years	0 days	<p>severe pain and swelling in left lower leg. Diagnosed with 2 DVTs 3 days later in emergency room.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1063600-1	65+ years	0 days	Patient received her second dose of the Pfizer vaccine today at 1330, she waited the required 15 minute observation time, was feeling fine and left. She returned to the vaccine clinic around 1415 reporting that she was having trouble breathing. Security called the charge nurses and alerted them that a patient needed assistance. Writer came out to patient who was seated in her car. We assessed patient who was visibly having difficulty breathing and was unable to respond to questions without difficulty breathing. Emergency medication box was opened and epinephrine was prepped. We assessed patient's allergies and recent medications taken. Patient denied hx of breathing problems or anxiety. Pt denied chest pain. Per protocol for potential allergic reaction, 0.3ml of epi was given at approximately 1426 via IM injection in the pt's left arm. ED triage nurse was called and asked to come assist. Two ED technicians with stretcher arrived and with writer accompanying them transported pt to ED.
COVID19 VACCINE	PFIZER\BIONTECH	1065435-1	65+ years	0 days	blood clot; death cause: Heart Problems; tired; nauseous; This is a spontaneous report from a contactable consumer. An 81-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number EL3248), via an unspecified route of administration at single dose in the left arm on 19Jan2021 14:00 for covid-19 immunisation. Medical history included heart problems, pacemaker. Concomitant medication included heparin. The patient experienced death cause: heart problems on 20Jan2021, blood clot on an unspecified date with outcome of unknown that required hospitalization, tired on 19Jan2021 with outcome of unknown, nauseous on 19Jan2021 with outcome of unknown. The patient was hospitalized for blood clot from 16Jan2021 to 18Jan2021. The patient died on 20Jan2021. An autopsy was not performed. The events were described as follows: The patient was tired and nauseous about 3 hours after her vaccine. She had been in the hospital 16Jan2021 to 18Jan2021 for a blood clot. The patient died at her home on 20Jan2021 between 4 and 7 pm. No treatment required. The vaccine was administered at Hospital Facility. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19.; Reported Cause(s) of Death: death cause: Heart Problems
COVID19 VACCINE	PFIZER\BIONTECH	1068886-1	65+ years	0 days	DEATH Narrative: Pt he reports he developed chills SOB body aches the same night as receiving the COVID vaccine on 1.26.2021-pt is currently reporting CheSt tightness and SOB Admitted to hosp: ICU with Bilateral Pulmonary Emboli, LLE DVT, NSTEMI, Arrhythmia.

COVID19 VACCINE	PFIZER\BIONTECH	1070714-1	65+ years	0 days	<p>she was hospitalized 2.5 days after having symptoms of a ""massive heart attack"" 2 days after the vaccine; blood clot; pain on the left side/pain so bad/ pain was so severe couldn't bent over and couldn't get up; pain was in the heart and underneath the rib; pain was in the heart and underneath the rib; had a little trouble breathing; broke out in a sweat; This is a spontaneous report from a Pfizer-sponsored program Pfizer First Connect from a contactable consumer (patient). A 77-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number/expiration date unknown), via an unspecified route of administration on an unspecified date in Feb2021 at a single dose for COVID-19 immunization. Medical history included asthmatic, had double pneumonia years ago, has ongoing atrial fibrillation and a pacemaker to control it as the only problem she has in her heart. The patient's concomitant medications were not reported. On an unspecified date in Feb2021, the patient was hospitalized for 2.5 days after having symptoms of a massive heart attack two days after the vaccine. It was reported that two days post vaccination, the patient was rushed to the hospital by ambulance as they thought she was having a massive heart attack. She added her symptoms lasted for hours, she had pain so bad that she was bent over and had a little trouble breathing. She said the pain was in the heart and underneath the rib, on the left side. She later mentioned she did not feel like it was AFib. She said they did every test possible and listed the following ones: ultrasound, stress test, x-ray (unknown results), and blood work in Feb2021. She specified that her blood work indicated a blood clot. She mentioned she was told by her personal friend, who was a doctor, that by having the shot sometimes it indicated you have blood clots when you really don't. The patient also specified that she broke out in a sweat, the pain was so severe that she could not bend over and could not get up; therefore, they treated her as if she was having a massive heart attack for 12 hours at the hospital. It was reported that they kept giving her stuff to stop the effect with her heart. She mentioned her second dose was scheduled on 25Feb2021. She asked if her experience was reported as a side effect to the vaccine and should she get the second dose of the vaccine. She explained the doctors did not know what she had, and she needed to determine if she can receive the second dose. She also asked if we could notify her if a similar reaction is reported. The outcome of the events was unknown. Information on lot/batch number has been requested.""</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1070763-1	65+ years	0 days	<p>large knot right above the injection site/size of a half dollar/size of a silver dollar and where the needle went in was right at the base of that knot/like egg under the skin or clot; felt like she got a flu shot and could tell her arm was very sore; swelling started almost immediately after the shot/swelling was exactly underneath the injection site, just in the pronounced area/about 4 inches wide and about 2 inches high; thought maybe someone has hit a vein because it did bleed and ran down her arm; This is a spontaneous report from a contactable consumer. A 66-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection, lot number: EN6201, unknown expiration), via an unspecified route of administration on 18Feb2021 at 04:30 at a single dose for COVID-19 immunization. Medical history reported as none. Concomitant medications included tolterodine and adalimumab (HUMIRA). The patient reported that she received the COVID vaccine on 18Feb2021 at around 4:30. Firstly it was fine, she felt like she got a flu shot and could tell her arm was very sore. What concerned her was the swelling started almost immediately after the shot on 18Feb2021. She knew that was one of the symptoms. This morning and yesterday though (18Feb2021), she noticed some of the symptoms. She got a large knot that was right above the injection site. Yesterday, it was about the size of a half dollar, today it is about the size of a silver dollar and where the needle went in was right at the base of that knot. It feels like an egg under the skin or a clot. Like a knot (a hard spot underneath the skin). The patient was wondering if it was something she should be concerned about because the swelling was exactly underneath the injection site, just in the pronounced area. It was a rectangle and is about 4 inches wide and about 2 inches high and then right above that was where the needle went in. The large circle or knot was right above that and she was thinking possibly when she was given the injection she has never really bleed before. So, she thought maybe someone has hit a vein because it did bleed and ran down her arm. She got no problem. That happens at times, but she started thinking if this was a clot or it was something that is right above there because it is so pronounced, and it really hurts. The patient stated that she took some Aspirin last night and is going to take an ibuprofen in a little while. She mentioned that she takes this one pill and it has nothing to do with anything. The patient had lab work done (unknown results) that was about 3 weeks ago (2021). She also stated that she also take Humira which is a shot every 2 weeks and it said in the fact sheet that she should be concerned or be sure that she did not take any medicine that affects the immune system and Humira does weaken the immune system but she was not ask that prior to. The patient wanted to know if is that something she should be concerned about. Outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1072556-1	65+ years	0 days	<p>right leg showed blood clot in lower back of leg from ankle to knee; right leg calf was red swollen and throbbled; Right leg ankle still hurt; flu symptoms appeared; Left arm, muscles, joints hurt; Left arm, muscles, joints hurt; Left arm, muscles, joints hurt; tired; chills; not feeling well; This is a spontaneous report from a contactable consumer (patient). A 70-year-old female non-pregnant patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EM9810), via an unspecified route of administration on 11Feb2021 10:00 at single dose in arm left for COVID-19 immunisation. There was no medical history and no known allergies. Concomitant medication included colecalciferol (D3) and multi vitamin. The patient did not have COVID prior vaccination. There was no other vaccine in four weeks. After about 4 hours after first Pfizer shot on a Thurs (11Feb2021), the patient experienced flu symptoms appeared, Left arm, muscles, joints hurt, chills, tired, not feeling well, on 11Feb2021 16:00. Right leg ankle still hurt after 24 hours Friday and Saturday by Sunday. Right leg calf was red swollen and throbbled on 14Feb2021 16:00. Monday (on 15Feb2021) the patient called physician and had sonogram on right leg which showed blood clot in lower back of leg from ankle to knee. Doctor put immediately on rivaroxaban (XARELTO) blood thinner for blood clot. Blood work has been done on 15Feb2021. The patient would follow up on 02Mar2021. She was concerned about taking second COVID vaccine dose on 04Mar2021. The adverse events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. Covid was not tested post vaccination. The event outcome was unknown.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1081108-1	65+ years	0 days	Cellulitis in left leg may be acting up/Might have an infection in area of cellulitis in left leg; Cellulitis in left leg may be acting up/Might have an infection in area of cellulitis in left leg; Questioned if she might have a blood clot in left leg; Might have an infection in area of cellulitis in left leg; pain in the left leg; This is a spontaneous report from a contactable consumer. A 72-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL9262, expiration date 31May2021), via an unspecified route of administration on 01Feb2021 at left upper arm around 19:00 or a little later at single dose (at the age of 72-years-old) for covid-19 immunization. Medical history included bad knees and got injections for this and recurrent cellulitis of legs (cellulitis was not active at time of vaccine; but anytime her leg swells with bad knees she had a little episode with the cellulitis down around her ankles on both legs but left leg was more predominant. She had been keeping it at bay), mineral supplementation, bad knee pain, blood pressure medication (abnormal), urine output control (abnormal), dehydrated and dizzy. Concomitant medication included lisinopril as blood pressure medication, potassium for Mineral supplement, solifenacin succinate for urine output control, paracetamol (TYLENOL 4) for bad knee pain. She had taken potassium before and it calmed it down: she was little dehydrated, little dizzy, so was drinking some Pedialyte, water, and taking potassium. The patient had it once before but it kind of snuck up on her again. The patient called to ask if anyone had reported any type of blood clot on the same side of the body that the Pfizer COVID-19 Vaccine was administered. She questioned if she might have a blood clot in her left leg after having been administered the Pfizer COVID-19 Vaccine. She had recurrent cellulitis in both legs prior to Pfizer COVID-19 Vaccine. The doctor thought the cellulitis in left leg may be acting up and that she might have an infection in that area of cellulitis. She reported pain in the left leg when she rested her leg on a pillow; but did not feel any pain when she was standing and walking. The pain became a little too hard for her to bear so the doctor prescribed her Cephalexin 500m capsule every 12 hours-she was on the 3rd capsule now. Onset date for the events was approximately 03Feb2021 or 04Feb2021. The events were better since started Cephalexin. Second dose date scheduled for 22Feb2021 but did not give her time. The outcome of the events was recovering. Follow-up (23Feb2021): New information received from the product quality complaint group includes confirmation of lot number (EL9262) and new expiry date.
COVID19 VACCINE	PFIZER\BIONTECH	1085254-1	65+ years	0 days	Severe abdominal pain unable to eat or sleep for 36 hours. He went by ambulance to the Hospital emergency room. They tried to pump his stomach but he aspirated and and went into cardiac arrest. He was revived but never regained consciousness. (The ICU Dr said that he had blood clots in his abdomen from a recent stroke. We were unaware of him having a stroke other than in 2026. The same Dr. said that he had necrosis in his lungs from aspirating. The necrosis was from his bowel dying) He was put on a ventilator and given drugs to increase his heart rate. On 3-5-21 the heart drugs were reduced and he died. I was with him when he recieved the vaccination and he was healthy, just old. I think that the shot killed him.
COVID19 VACCINE	PFIZER\BIONTECH	1087883-1	50-59 years	0 days	I had my first shot of Pfizer vaccine last Friday morning (March 5). In the evening, I felt fatigued. So I went to sleep early. When I got up Saturday morning, I felt dizzy. The dizziness went away in a few minutes. In the next 36 hours, I had the angina feelings - tightness in the left chest and I felt heart be squeezed occasionally. When I stand up and walk, I felt better. Finally Sunday evening (March 7), I took a walk outside and felt symptom free. Maybe the walk helped, maybe the ""thrombosis"" had run its course before my walk. I have not had the severe angina symptoms since my PCI procedure in Feb 2018. I am sure the recent occurrence is related to the vaccine. Besides reporting the adverse event, I want to get advices whether I should receive the second shot. Thank you!""
COVID19 VACCINE	PFIZER\BIONTECH	1088612-1	40-49 years	0 days	got vaccine - about a week later - she sent us a message saying ""I have been having right calf pain for about a week or more. I have more increased SOB and chest pain."" was able to get ddimer which was elevated - and was admitted to the hospital for this since her vaccine - she has noticed increased chest tightness, SOB, hairloss, DVT/PE.""

COVID19 VACCINE	PFIZER\BIONTECH	1090229-1	60-64 years	0 days	pulmonary embolism/Blood clots in the lung; heart attack; Shortness of breath; headache; jaw hurt; Shin hurt; heart burn; This is a spontaneous report from a contactable consumer (patient's son). A 63-year-old female patient (mom) received the second dose of BNT162B2 (Pfizer-Biontech Covid-19 Vaccine), via an unspecified route of administration in arm in Feb2021 (reported as in the first week of Feb2021) at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Patient previously received the first dose of BNT162B2 in Jan2021 for COVID-19 immunization. Reporter (patient's son) received his first dose of Pfizer COVID vaccine on Wednesday and wanted to know if this vaccine could cause blood clot. He stated his mom (patient) in the hospital due to pulmonary embolism from 24Feb2021, 2.5 weeks after her second shot. He stated his anxiety levels were higher than normal. He had strong response to flu vaccine this year and experienced chill, shakes, fever, received antibiotic, and loss sense of taste from the flu vaccine. Reporter read online that some people commented that they have DVTs (deep vein thrombosis) and blood clots from the Pfizer COVID vaccine. Patient experienced blood clots in the lung in Feb2021 and hospitalized on 24Feb2021. Patient got her second shot about 2 weeks before and she ended up in the hospital with pulmonary embolism. They looked at her lungs and found all the blood clots. Patient had really bad shortness of breath, headache, her jaw hurt, and her shin hurt. She was helping out at vaccine clinic and she was out of breath, she said the old people in strollers were passing her. Patient began to make complaints about how she was feeling in mid of Feb2021. Patient said in rare cases 2 weeks after the second dose reactions could happen. Patient got done working in ICU, and helped with PPE, then at 11 she left work at the hospital, she was experiencing heart burn for 3 days and so she thought had a heart attack drove to an ER (emergency room) on the way home, and then was admitted to the hospital on that same day 24Feb2021, she was supposed to be discharged today (26Feb2021). Patient had been feeling out of breath for past 2 month, it was possible it might seem like it was related to the vaccine but it could also not be related. Reporter stated that on the internet he saw how a 1000 deaths happened after the vaccine, it was all old people, but in the autopsies there was no link to the vaccine, they were going to die regardless. Lab data included: She did get a test before for Factor 5 Leiden but it was negative. They did test for COVID, it was negative, while in the hospital. In the hospital they were also testing her again for the Factor 5 Leiden, the results hadn't come back yet. They did test for blood clots, they did an MRI (magnetic resonance imaging) in Feb2021, it was positive for blood clots (blood clots in the lungs). When she was admitted her oxygen was 85%. Outcome of the events was unknown. Information on lot and batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1093491-1	65+ years	0 days	Blood clot, swelling noticed a few hours after vaccine. Probably coincidence but felt it should be reported. Im not sure if the doctor she saw for blood clot knew she got the vaccine. It was a different clinic.
COVID19 VACCINE	PFIZER\BIONTECH	1095382-1	30-39 years	0 days	Swollen lymph node right groin started about 6-8 hrs after vaccination. Over next 48 hours below that lymph node down to the right knee increasingly red, swollen rash, pain. ER visit diagnosis Lymphangitis. Treated with IV antibiotics then released 7am 12 March. Treatment with clindamycin(450mg) 3x daily for next 7 days. Rest and elevate leg. 12 hours after treatment began, feeling better not well yet. Swollen lymph node appears to be mostly gone and painful swollen rash has been reduced.
COVID19 VACCINE	PFIZER\BIONTECH	1101062-1	65+ years	0 days	Chest and Shoulder pain, shortness of breath, extreme pain when inhaling, Pulmonary Embolism diagnosed at hospital after ct scan and blood tests showed several lung infarctions, given xarelto for 6 months and follow up with gp. and tylenol for pain
COVID19 VACCINE	PFIZER\BIONTECH	1102512-1	30-39 years	0 days	I received my first dose Pfizer vaccine on 03-09-2021. I have a history of blood clot, 10 years ago. I am currently 9 weeks pregnant. I called my doctor's office who encouraged me to go to the ER since I was having symptoms of a blood clot. I went to the emergency room at Hospital where they did some blood testing. I then went to Hospital where they did more lab work and blood testing, they did a D-dimer test and my level was at 3.23 and explained to me it could be due to my pregnancy. They ran some more tests showing I have a clot in the superficial femoral/ popliteal vein. They placed me on Lovenox medication for two days. I will be seeing a maternal fetal doctor tomorrow for further evaluation. They also monitored my baby and baby is doing fine.
COVID19 VACCINE	PFIZER\BIONTECH	1103410-1	65+ years	0 days	Developed a DVT blood clot in right leg calf area -after the shot-

COVID19 VACCINE	PFIZER\BIONTECH	1103636-1	65+ years	0 days	<p>He has had a friable capillaries, so sometimes when he urinate, he urinate blood or little blood clots; This is a spontaneous report from a contactable consumer. A 78-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EN6198), via an unspecified route of administration on 24Feb2021 at a single dose for COVID-19 immunization and apixaban (ELIQUIS), via an unspecified route of administration from an unspecified date to an unspecified date at unknown dose for Atrial Fib (atrial fibrillation). Medical history included prostate cancer from about 10 years ago and was treated by radiation, the radiation has caused capillaries in the penis to be fragile (friable capillaries) and there were times when he bleeds and has some clots and it usually resolves itself; and bloody urine in the past. The patient's concomitant medications were not reported.. Radiation has caused capillaries in the penis to be fragile and there are times when he bleeds and has some clots. The patient has had a friable capillaries, so sometimes when he urinates, he urinate blood or little blood clots. The patient was on Eliquis, so yesterday when they came home after he got the vaccine, he was bleeding with the clots which he has done in the past. The reporter asked if it is possible that the vaccine can precipitate a bleeding episode in someone that is on Eliquis and had on and off had bloody urine in the past. After the shot, he was bleeding with the clots and with the bloody urine. The patient got the first dose of the Pfizer COVID-19 vaccine on Wednesday. He had radiation for prostate cancer 10 years ago. He had a bloody urine periodically and the doctors were aware. He had a blood urine one hour post vaccination in 24Feb2021. It would take at least a few hours for the medication to get in the system before having any kind of reaction. It resolved on its own he doesn't have a blood urine anymore. The second dose of the vaccine is due on 16Mar2021. The action taken in response to the events for apixaban was unknown. The outcome of the events was recovered on unspecified date in Feb2021.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1113713-1	65+ years	0 days	<p>My mother called me when she was going to get her second vaccination. She was alive and well and living independently at her home. She could walk, talk, make her own food, wash and dry her own clothes and take her own baths. After taking the second vaccination she went down hill. She became sicker and sicker and eventually she started coughing up blood. She decided to go to the hospital, another Hospital of facility. I don't know what the treatment was at that hospital but she was soon transferred to facility and that is where I was notified she was in the hospital and visited her there. After arriving they intubated her and said she had blood clots in her brain and heart. When I saw her after she transferred from Hospital to the Hospital I noticed one arm was swollen. Her legs were as they have been for the last 20 years and looked okay to me—no discoloration other than her regular discoloring at one right ankle and the same old same old slight swelling in the left ankle. The doctors and nurses were putting the blame on her legs but you could tell things were happening else where. But as she got worse and worse at the hospital her right arm become more and more swollen with dark bruises appearing—the hospital staff took pictures. The left arm continued to swell and did not look normal at all. She apparently had bleeding in her left lung from a blood clot. She had three areas of her brain that add clots and some bleeding. She was constipated and gaseous when they cleaned her. They didn't treat her constipation which made being intubated worse because I feel that caused her intestines to swell, thus she also had bleeding in her intestines. My mother died on March 17, 2021 at hospital in ICU. I was told they could not treat the blood clots because of the bleeding in her lung, intestines and brain.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1113951-1	Unknown	0 days	pulmonary embolism; shortness of breath; dizziness; This is a spontaneous report from a contactable nurse. A 76-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on 22Feb2021 (batch/lot number was not reported) as single dose for COVID-19 immunisation; and apixaban (ELIQUIS), via an unspecified route of administration from Feb2021 (batch/lot number was not reported) to an unspecified date, at unspecified dose for an unspecified indication. The patient's medical history and concomitant medications were not reported. The patient previously received first dose of bnt162b2 on an unspecified date for COVID-19 immunization. On Feb2021, three weeks following the patient's TK (unspecified), patient experienced shortness of breath, dizziness (notable with exertion), and pulmonary embolism. The patient underwent lab test and procedure which included body mass index: 42.19 on Feb2021. Outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Based on the information provided, the reported pulmonary embolism is likely an intercurrent medical condition in this 76 year old female patient and unrelated to BNT162B2. Of note, medical history and indication for apixaban were not provided to determine pre-existing risk factors that may have led to the event. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1117948-1	40-49 years	0 days	Patient had calf swelling and then more after Covid Vaccine. Patient then had SOB. Patients primary obtained dopplers and CT chest, which showed DVT's and PE. Patient had shoulder surgery 3 months ago, is more sedentary than had been.
COVID19 VACCINE	PFIZER\BIONTECH	1119101-1	65+ years	0 days	The patient developed a pulmonary embolism three days after the second dose, shortness of breath, hypotension, tachycardia.
COVID19 VACCINE	PFIZER\BIONTECH	1121620-1	65+ years	0 days	chest pains; chest pains; blood clot; light headedness; low fever; blacked out for about 5 minutes; onset of major body ache and fatigue; onset of major body ache and fatigue; Body aches at injection site and into upper back; Body aches at injection site and into upper back; This is a spontaneous report from a contactable consumer (patient). A 67-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EN6200), via an unspecified route of administration, administered in left arm on 23Feb2021 10:30 AM (at age of 67 years old) as single dose for COVID-19 immunisation. Medical history included high cholesterol. Concomitant medications included atorvastatin; levobunolol (eye drops); latanoprost (LATANO). The patient previously received his first dose of BNT162B2 on 05Feb2021 for COVID-19 immunisation (brand=Pfizer; lot number: EL9269; administration time 03:30 PM; vaccine location=Left arm; dose number=1). 6 hours after injection on 23Feb2021, the patient experienced body aches at injection site and into upper back. After 24 hours after injection on 24Feb2021, started light headedness, low fever, blacked out for about 5 minutes, onset of major body ache and fatigue. Spent the next 36hrs in bed. 72hrs after injection recovered back to normal slowly. On 04Mar2021 at 8pm, started with chest pains called, admitted to Hospital with heart attack, immediately taken to Cardiac Cath Lab for coronary catheterization in both legs, to partial remove blood clot and insert continuous balloon pump, IV Heparin infusion Troponin 6542.3 ng/l (critical), NO previous health issues for blood clots. Discharged 07Mar2021, Apixiban 5mg twice a day, Clopidogrel 75 mg /day. AE resulted in: Emergency room/department or urgent care, Hospitalization, Prolongation of existing hospitalization (vaccine received during existing hospitalization), Life threatening illness (immediate risk of death from the event. Number days hospitalization: 3 days. The outcome of events was unknown.

COVID19 VACCINE	PFIZER\BIONTECH	1122740-1	50-59 years	0 days	left calf pain/ significant DVT in left quad; This is a spontaneous report from a contactable consumer (patient). A 51-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection, Lot number: EL9264, unknown expiration), via an unspecified route of administration in left arm on 18Feb2021 as single dose for COVID-19 immunisation. Medical history included rheumatoid arthritis and Leiden factor 5. Concomitant medications included etanercept (ENBREL); gabapentin; meloxicam; and vitamin D3. The patient previously took Keflex and experienced allergies. The patient also received first dose of BNT162B2 (Lot number: GL9261, unknown expiration) in left arm on 28Jan2021 at 01:00PM for COVID-19 immunization. On the night of second dose on 18Feb2021 at 08:00 PM (20:00), the patient experienced left calf pain. Then quad pain started 2 weeks later along with the return of calf pain. The patient was diagnosed on 15Mar2021 with a significant DVT in left quad. The patient did not receive other vaccine in four weeks. The patient had no COVID prior to vaccination and not tested for COVID post vaccination. The event significant DVT in left quad resulted in doctor or other healthcare professional office/clinic visit, Life threatening illness (immediate risk of death from the event). The patient is currently on blood thinners as treatment. The patient is recovering from the event. No follow-up attempts are possible. No further information is expected.
COVID19 VACCINE	PFIZER\BIONTECH	1123622-1	65+ years	0 days	- day after vaccine developed cough productive of white mucus, dyspnea on exertion. Finally sought care 3/17 due to progression of symptoms and was found to have bilateral pulmonary emboli. No DVTs. No risk factors for PE. No prolonged immobilization, travel, surgeries, obesity, active cancer. - COVID negative rapid and PCR test on admission. No known prior COVID infection.
COVID19 VACCINE	PFIZER\BIONTECH	1127716-1	50-59 years	0 days	Shortness of breath, chest heaviness onset 1 week. 1st vaccine injection 2/17/21, 2nd vaccine 3/17/21
COVID19 VACCINE	PFIZER\BIONTECH	1133042-1	50-59 years	0 days	Pulmonary embolism. SOB; Left upper extremity dialysis graft occlusion necessitating balloon and stent; This is a spontaneous report from a contactable physician. A 51-years-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) intramuscular in arm right on 25Feb2021 at single dose for COVID-19 immunisation. Medical history included end stage renal disease (ESRD) on HD due to hypertension (HTN), and morbid obesity. The patient was allergic to Levaquin, NSAIDs. Concomitant medications included acetylsalicylic acid (ASPIRIN), atorvastatin, donazepam, dutasteride, escitalopram, metoprolol, nifedipine, sevelamer, torsemide, cetirizine hydrochloride (ZINE). On 25Feb2021, the patient had left upper extremity dialysis graft occlusion necessitating balloon and stent on the day of the vaccine administration. Pulmonary embolism developed 3 weeks after the first vaccine dose (Mar2021). No leg swelling, no long-distance travel, no immobilization or other cause of pulmonary embolism identified. No cough or fever. Shortness of breath (SOB) developed the day before the Pulmonary embolism (PE) was diagnosed (Mar2021). AEs resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event). The patient hospitalized for 2 days, received Heparin drip followed by Xarelto as treatment. Events outcome was recovering. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information provided the company cannot completely exclude a contributory role of BNT162b2 administration in the development of the reported 'complication associated with device and pulmonary embolism', with SOB as initial sign and symptom associated with pulmonary embolism. The impacts of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1137173-1	65+ years	0 days	Superior mesenteric vein thrombosis. No known cause at this time. Hypercoag panel negative. patient hospitalized and currently on Xarelto for 6 months. Received vaccination dose 2 1 week prior.
COVID19 VACCINE	PFIZER\BIONTECH	1147541-1	50-59 years	0 days	Pain in left arm . Tension in arms and shoulders. Shortness of breath. On 3/19/2021 I was diagnosed with pulmonary embolisms in both lungs and right leg
COVID19 VACCINE	PFIZER\BIONTECH	1147787-1	65+ years	0 days	Multiple pulmonary embolism 100 degree fever Chills incontinence Gout Blood Uric Acid Increase Shortness of breath

COVID19 VACCINE	PFIZER\BIONTECH	1150383-1	50-59 years	0 days	<p>blood clots in arm/Blood Clots in Left Arm; swollen lymph nodes /Swollen Lymph Nodes in Left Arm; nodules were found on her lungs/Nodules in Lungs; arm swelling /Left Arm Swelling; Left Arm Redness; Left Arm Discomfort; Soreness at the Injection Site; This is a spontaneous report from a contactable consumer (Patient's Mother) calling on behalf of daughter. A 50-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, batch/lot number and expiration date unknown), via an unspecified route of administration, administered in Arm Left on 05Mar2021 13:30 at age of 50 years old at single dose for covid-19 immunisation. There was no medical history. There were no concomitant medications. The patient did not have prior vaccinations within 4 weeks. No adverse events following prior vaccinations. There were no additional vaccines administered on same date of the Pfizer suspect. The patient experienced the following after first dose. The patient experienced arm swelling /left arm swelling (hospitalization) on 09Mar2021 with outcome of recovering , blood clots in arm/blood clots in left arm (hospitalization) on 11Mar2021 with outcome of not recovered , swollen lymph nodes /swollen lymph nodes in left arm (hospitalization) on 11Mar2021 with outcome of not recovered , nodules were found on her lungs/nodules in lungs (hospitalization) on 11Mar2021 with outcome of unknown , soreness at the injection site on 05Mar2021 with outcome of not recovered , left arm discomfort on 08Mar2021 with outcome of not recovered , left arm redness on 09Mar2021 with outcome of not recovered. The patient was hospitalized from 11Mar2021 to 12Mar2021. On 05Mar2021 she began to have arm pain. 48 hours later, patient's arm started really hurting her, something about her arm being sore on the day of injection and reporter said she was going to be sore and when she got back from going away for the weekend, she thought uh oh, there was a problem here, this was not normal, not right. On 10Mar2021, she experienced swells arm swelling and went to urgent care which was diagnosed with swollen lymph nodes and given Cheplex prescription at urgent care. 11Mar2021, daughter was admitted to hospital by her provider. Daughter was found to have blood clots in arm and continued swollen lymph nodes. Daughter was given IV cheplex and Eliquis while in hospital. Daughter will have to be on Eliquis for next 3 months per reporter. The patient had her first vaccine, Pfizer, and became ill with blood clots, swollen lymph nodes, and wound up in the hospital. Reporter stated that she and the patient were worried about her getting the second shot. The patient was on blood thinners and was seeing a pulmonary doctor and hematologist. She didn't know about her getting the second shot and thought this should be reported. The patient was due for the second vaccine next week on 26Mar2021 and she was still sick, should it be postponed or what? The patient went the night before the hospitalization to the Urgent Care and the doctor prescribed Keflex, an antibiotic and saw her primary care doctor the next morning and she put her in the hospital. Reporter stated they were getting nervous and wanted to report for side effects. She stated the patient was home from the hospital but still sick really bad. The patient went to Urgent Care 10Mar2021, saw her primary care 11Mar2021 and was sent to the hospital 11Mar2021. Reporter later clarified that the patient was sent to the Emergency Room and after a few hours, she was sent upstairs to be admitted for a 24 hour hospital stay. The patient received Eliquis; Keflex as treatment. Fluids</p>
COVID19 VACCINE	PFIZER\BIONTECH	1153367-1	65+ years	0 days	<p>left leg was cold/left foot was 79-82 degrees Celsius; blood clots in his left leg/he had three/first one on 02Mar, second one 13Mar and the third one yesterday; he had the Pfizer vaccine on 15Feb and 26Feb; he had the Pfizer vaccine on 15Feb and 26Feb; This is a spontaneous report from a contactable consumer (patient). A 77-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), second dose via an unspecified route of administration on 26Feb2021 (Batch/Lot Number: EN6203) as single dose for covid-19 immunisation; tafamidis (VYNDAMAX), route of administration, start and stop date, batch/lot number and dose were not reported for an unspecified indication. The patient took the first dose of PFIZER-BIONTECH COVID-19 VACCINE on 15Feb2021 at age of 77 years old for covid-19 immunisation. The patient medical history and concomitant medications were not reported. A patient taking Vyndamax medication who stated that he had experienced blood clot in his left leg. Clarified that he had the Pfizer vaccine on 15Feb2021 and 26Feb2021. Clarified that on 02Mar2021 that he had blood clots in his left leg. Stated that he had three. Stated that he had the first one on 02Mar2021, second one 13Mar2021 and the third one yesterday (15Mar2021). Stated that he was told left leg was cold. Stated that he took his temperature with a thermometer and his left foot was 79-82 degrees Celsius. Stated that the right foot is 95-96 degrees Celsius. Stated that he filled it out for the Covid vaccination. Stated that he reported Vyndalink when it asked what other medications that he took. The action taken in response to the events for tafamidis was unknown. The outcome of events was unknown.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1153425-1	40-49 years	0 days	Deep vein thrombosis in right calf; received bnt162b2, dose 2 on 15Jan2021/first dose on 29Dec2020; received bnt162b2, dose 2 on 15Jan2021/first dose on 29Dec2020; This is a spontaneous report from a contactable physician (patient). A 45-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in the left arm on 15Jan2021 (Batch/Lot number was not reported) at a single dose for covid-19 immunisation. The patient received the first dose on 29Dec2020 in the left arm for covid-19 immunisation. The patient did not receive any other vaccines in four weeks. Medical history included allergies: Sulfa. Patient was not pregnant at the time of report. The patient has not had COVID prior vaccination and was not tested post vaccination. Concomitant medication included ethinylestradiol, levonorgestrel (SEASONIQUE) taken for birth control. The patient experienced deep vein thrombosis in right calf on 13Feb2021 with outcome of recovering. The event deep vein thrombosis in right calf resulted in doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The patient received aspirin regimen as treatment for the event deep vein thrombosis in right calf.; Sender's Comments: Based on the information currently available, the event deep vein thrombosis most likely represents an intercurrent medical condition and was unrelated to Bnt162b2 vaccine. A possible contributory role of concomitant drug ethinylestradiol, levonorgestrel to the event can not be totally excluded. Case will be re-assessed upon the additional information provided. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1159981-1	30-39 years	0 days	hemorrhagic bleeding (period), blood clot via bleeding. 1 week of bleeding, required transfusion cbc/esr/crp. now have +factors for antiphospholipid syndrome along CCP. along w/ joint pain in her right hands, fingers and right knee. have swelling to the fingers.
COVID19 VACCINE	PFIZER\BIONTECH	1160745-1	40-49 years	0 days	Patient complains of shortness of breath about 5-10 min after vaccine. BP was taken because patient stated she has high BP and a history of stroke. BP was 158/114. 911 was called and ambulance arrived in 10-15min. EMT assessed patient and asked her to smile. Patient's left face was not responding normally, Patient asked to lift both arms. Patient could not fully lift both arms. Patient transported to hospital.
COVID19 VACCINE	PFIZER\BIONTECH	1174347-1	65+ years	0 days	She had a stroke on 3/28/2021 due to a blood clot in her brain; She had a stroke on 3/28/2021 due to a blood clot in her brain; Administration_date=08/03/2021 number=1/administration_date=22/03/2021 number=2; Administration_date=08/03/2021 number=1/administration_date=22/03/2021 number=2; This is a spontaneous report from a contactable consumer reporting for herself. A 66-years-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: Unknown), via an unspecified route of administration, administered in Arm Right on 22Mar2021 17:45 (vaccinated at the age of 66 years old) as single dose for covid-19 immunisation. Patient received the first dose on 08Mar2021. Medical history included diabetes; obesity; high blood pressure, iodine allergy. The patient's concomitant medications were not reported. The patient experienced she had a stroke due to a blood clot in her brain on 28Mar2021 18:30, The patient was hospitalized for she had a stroke due to a blood clot in her brain (cerebrovascular accident) for 2 days. Patient visited Emergency room/department or urgent care for events a stroke due to a blood clot in her brain and received treatment. Outcome of event a stroke due to a blood clot in her brain was not recovered. Information about lot/batch number requested.

COVID19 VACCINE	PFIZER\BIONTECH	1175188-1	65+ years	0 days	<p>extensive proximal right lower extremity deep vein thrombosis; This is a spontaneous report received from a contactable physician. A 68-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number not reported) via an unspecified route of administration, at the age of 68-year-old, on 05Mar2021, as SINGLE DOSE for covid-19 immunisation. Medical history included hypertension and chronic kidney disease. The patient's concomitant medications were not reported. The patient experienced extensive proximal right lower extremity deep vein thrombosis (medically significant) on 05Mar2021. Therapeutic measures taken as a result of extensive proximal right lower extremity deep vein thrombosis included anticoagulation agent. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination the patient was not diagnosed with COVID-19 and has not been tested for COVID-19. Outcome was recovering at the time of the report. Information about batch/lot number has been requested.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1182734-1	65+ years	0 days	<p>break in rash/rash in mouth and throat; sore throat; dizzy; weak; felt like sleeping all the time; pain in her arm; blood clot in right leg; couldn't walk; veins are swollen; right knee got swollen; ear ache; felt like burning/ sore in her mouth like she was burned; sore in her mouth like she was burned; nausea; headache; slight fever; This is a spontaneous report from a contactable consumer (patient). An 81-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration in right arm on 09Mar2021 (Lot Number: EL9266) at single dose for covid-19 immunization. Medical history included arthritis, respiratory issues, allergies, Eczema of the nipples and breast, arthroscopic surgeries, she lost her voice. Caller stated she exercised everyday, she did yoga. Caller reported the last 2 years she hadn't been able to climb the mountain on the stairs. Caller states she didn't catch a cold, she was fine, she was very active. She was good except arthritic conditions, she has had arthroscopic surgeries, that was a side effect of that. Caller reporting she was a first responder and had some respiratory issues. Caller stated she had some allergies, if with dust or smoke, her throat constricts, it was just small, like her throat. She cannot be around that. She got once in a while, when she got in a rush. Caller stated before the vaccine, she had eczema in her nipples, on her breast. Caller stated she never got sick, besides the rash she got once in a while. Caller states but she was very healthy otherwise, no medication, no smoking, no drinking. Caller stated she was from 9/11, this was what happened with her voice once in a while, she lost her voice. Caller stated she had had some respiratory issues and allergies and so on. Caller stated she was here for 56 years and her mother died of old age so she was not sure. There were no concomitant medications. The patient previously took advil. Caller stated she used to take Advil when she went to the gym and had problems but she hasn't taken Advil for a while. She didn't take meds. Caller stated she didn't drink or smoke because what it did was it gave you a release. Caller stated she was not taking none, she was pushing through and hoping it will heal itself. The patient experienced blood clot in right leg on 26Mar2021, break in rash on an unspecified date, headache on 09Mar2021, slight fever on 09Mar2021, veins are swollen on 12Mar2021, right knee got swollen on 12Mar2021, sore throat on an unspecified date, ear ache on 10Mar2021, nausea on 09Mar2021, rash in mouth and throat on an unspecified date, felt like burning/ sore in her mouth like she was burned on 10Mar2021, sore in her mouth like she was burned on 10Mar2021, dizzy on an unspecified date, weak on an unspecified date, felt like sleeping all the time on an unspecified date, couldn't walk on 12Mar2021, pain in her arm on an unspecified date. Was a first responder, sometimes break in rash once in a while. Got Pfizer 1st vaccine 09Mar, was scared to have difficulty breathing however had headache, slight fever, right knee and veins were swollen, sore throat, ear ache, nausea, rash in mouth and throat also felt like burning also was dizzy and weak and felt like sleeping all the time. Caller stated she was told by her doctor to take the shot on 09Mar2021. Caller stated she had headache, slight fever, then her head was ok the fever was gone but the headache persisted as of today. Caller stated she still had headache and ear ache and her knee got swollen, her right knee. Caller stated for a few days she couldn't walk. Caller reported she has arthritic conditions in knees, she exercises everyday and no problem, but she couldn't walk for a few</p>

COVID19 VACCINE	PFIZER\BIONTECH	1190955-1	65+ years	0 days	<p>blood clot in the lung; my left leg from the knee down started to swell; my left leg from the knee down started to swell, get really hard and became very painful/I could hardly walk and after and pain was so intense; my left leg from the knee down started to swell, get really hard and became very painful/I could hardly walk and after and pain was so intense; blood clot in the leg; This is a spontaneous report from a contactable consumer (patient). A 69-year-old female patient (patient was not pregnant at the time of vaccination) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Lot number: EN3248, Expiry date: unknown) via an unspecified route of administration, administered in left arm on 16Feb2021, 15:30 PM at a single dose for covid-19 immunisation (age at vaccination was 69 years). Medical history included blood pressure and thyroid. Concomitant medication patient received within 2 weeks of vaccination included levothyroxine, valsartan, furosemide, acetaminophen. No other vaccine was received within 4 weeks prior to the COVID vaccine. On 16Feb2021, 3 hours after the patient received the vaccination at 18:30 the patient's left leg from the knee down started to swell, got really hard and became very painful. She could hardly walk and afterwards the pain was so intense that she went to the doctor. Doctor took X-rays of her left leg on 16Feb2021, then he diagnosed her with blood clots. He gave the patient 2 heparin shots and immediately sent her to the hospital for a deep vein ultrasound on 16Feb2021. The results showed blood clot in the leg. The patient was prescribed medication and sent home. Her leg continued to be rock hard and painful. On 02Mar2021, the patient was sent for a blood panel work up. There was no improvement. On 08Mar2021, the doctor sent her for a lung CT scan. On the same evening, the patient was called to the doctor's office and was sent to ER immediately as the results showed blood clot in the lung. The patient's dose of Eliquis was doubled. This has now been going for 5 weeks, the patient had not been without pain during this time. Her left leg hardness had gone down a little but was still twice the size of her right leg, knee was huge. The swelling never goes down, not even at night. No covid prior vaccination and no covid tested post vaccination was reported. This case was reported as serious. The outcome of all the events was not recovered. No follow-up attempts are possible. No further information is expected.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1190985-1	65+ years	0 days	<p>PT devolved occlusive DVT to left femoral vein; This is a spontaneous report received from a contactable physician. A 77-year-old male patient received second dose of BNT162B2 (Batch/Lot number and expiry date was not reported), via an unspecified route of administration on 24Mar2021 at single dose in the left arm for COVID-19 immunisation. The patient's medical history was not reported. Concomitant medication(s) included azithromycin (Z-PAK) taken for an unspecified indication, start and stop date were not reported. The patient experienced ""devolved occlusive DVT to left femoral vein"" on 24Mar2021 with outcome of unknown. The adverse event resulted in Doctor or other healthcare professional office/clinic visit and Emergency room/department or urgent care. Therapeutic measures were taken as a result of occlusive dvt to left femoral vein which included apixaban (ELIQUIS). The patient did not receive any other vaccines within four weeks prior to the vaccination. Prior to the vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Information on the lot/batch number has been requested.; Sender's Comments: Based on the close temporal relationship, the association between the event ""occlusive DVT to left femoral pain"" with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.""</p>
COVID19 VACCINE	PFIZER\BIONTECH	1194661-1	18-29 years	0 days	<p>had headache rest of the day, mild and tolerable, most of thursday had headache and body aches was able to work. Friday I felt better friday night I started to get a headache again this time only on my right side, with lots of pressure. Saturday I had pressure and dull headache all day, I took Tylenol and Ibuprofen with no relief. Sunday I went to urgent care the headache was much worse now on the left side of my head, urgent care misdiagnosed me as having a sinus infection. Early monday morning I work up to a hard pulsing pain in my head, went to the ER where they found I had two blood clots in my brain (acute cerebral sinus thrombosis), one significant one obstructing blood flow and one much smaller one.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1200719-1	65+ years	0 days	She had a stroke caused by blood clot in brain. Suffered a second stroke 4 weeks later. Has weakness left leg. Is now in Rehab Center
COVID19 VACCINE	PFIZER\BIONTECH	1201033-1	50-59 years	0 days	at 11:30 pm on 4/7/21 I had extreme, spontaneous, stomach cramps so bad I thought I was going to pass out, that lasted for one hour, then diarrhea. A few hours later I started blood red rectal bleeding. At the hospital I was diagnosed with Ischemic colitis (from colonoscopy) and a blood clot was also found, portal vein thrombosis. I am 100% certain the extreme stomach cramps were brought on by the vaccine and that in turn caused the ischemic colitis, the blood clot may or may not have already been there. Note: The Dr.'s were not interested to tie any relation to this episode with the vaccine which was quite frustrating as it was quite obvious
COVID19 VACCINE	PFIZER\BIONTECH	1203198-1	50-59 years	0 days	Second vaccine received on 4/6/21. Pulmonary Embolism on 4/11/21. Death on 4/13/21.
COVID19 VACCINE	PFIZER\BIONTECH	1205255-1	40-49 years	0 days	Went to ER and was diagnosed with bilateral pulmonary emboli; Pain on left lung/torso/Severe pain on left lung/torso, pain starting at collar bone down the torso; increased difficulty breathing; Vomiting; fever 99.2/fever 99.6; Tired; Nausea; This is a spontaneous report from a contactable consumer. A 46-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: ER 8727), via an unspecified route of administration, at the age of 46 years, administered on the left arm on 23Mar2021 10:45 at a SINGLE DOSE for covid-19 immunisation. Medical history included drug hypersensitivity to PCN from an unknown date and unknown if ongoing. Concomitant medications included ethinylestradiol, norgestimate (TRI-SPRINTEC) and fluoxetine (FLUOXETINE); both taken for an unspecified indication, start and stop date were not reported. The patient previously took amoxicillin and experienced drug hypersensitivity. The patient went to ER and was diagnosed with bilateral pulmonary emboli on 23Mar2021 21:30, pain on left lung/torso/severe pain on left lung/torso, pain starting at collar bone down the torso on 23Mar2021 21:30, increased difficulty breathing on 23Mar2021 21:30, nausea, vomiting, fever 99.2/ 99.6, tired on 23Mar2021 21:30. The patient underwent lab tests and procedures which included body temperature: 99.2 on Mar2021, body temperature: 99.6 on Mar2021, sars-cov-2 test: negative on 01Apr2021. Therapeutic measures (Eliquis (blood thinners)) were taken as a result of the events. The events were reported as Life threatening. The outcome of the events was recovering.
COVID19 VACCINE	PFIZER\BIONTECH	1208484-1	65+ years	0 days	3hrs after the patient's vaccination, she fell to the floor and was unable to get up, noted to have R sided facial droop, inability to speak, R sided weakness. Found to have a large stroke with left sided M2 MCA clot noted on CT angiogram.
COVID19 VACCINE	PFIZER\BIONTECH	1209217-1	60-64 years	0 days	4/9/21-30 minutes to 1 hour after receiving 2nd dose of vaccine patient had bloody nose, clots, with bleeding sores on tongue and side of mouth. Began to have bruises on arms, feet and legs. Blood in urine and bruises on back. Presented to emergency department on 4/11/21. CT brain revealed a right sided posterior temporal hemorrhage. Patient was emergently treated with platelets, DDAVP, factor VII, Decadron, IVIG. 4/12/21, patient denies headache, changes in vision, double vision, change in sensation, including burning, pinprick, numbness, no focal or motor weakness. No change in bowel or bladder control. No sensory changes. Patient states she is now back to her normal state of health, save for the bruising described.
COVID19 VACCINE	PFIZER\BIONTECH	1218929-1	50-59 years	0 days	After patient received the vaccine the following events occurred: - Office visit with PCP 4/14/2021. Complaints consisted of chest pain, SOB, left shoulder and left breast soreness and pain, difficulty sleeping. CT and EKG test ordered and performed. - CT result showed bilateral Pulmonary Embolism. - Lower extremity doppler ultrasound was also performed and negative. Patient is still admitted to hospital and awaiting overall outcome.
COVID19 VACCINE	PFIZER\BIONTECH	1219835-1	65+ years	0 days	DVT – leg pain began the day after vaccination, patient was seen in the ER a week later and diagnosed with right leg DVT. Started treatment with Eliquis.
COVID19 VACCINE	PFIZER\BIONTECH	1219999-1	65+ years	0 days	Patient developed left leg pain and swelling a few days after receiving her second Pfizer COVID19 vaccination. She was seen in the ER and found to have extensive iliofemoral DVT of the left leg. She was taken for a venogram and thrombectomy and then started on Eliquis.

COVID19 VACCINE	PFIZER\BIONTECH	1224338-1	65+ years	0 days	<p>Lower chest partial atelectasis or scarring in the lung bases bilateral; Partial lung collapse (both upper and lower parts collapsed); Lower chest partial atelectasis or scarring in the lung bases bilateral; Beneath this area was a red circle where blood clotted or something; Wheezing; Shortness of breath; Swelling of the face; underneath the arm where the injection site was, a big red circle was noted and it was swollen/under her nose and left elbow were red; underneath the arm where the injection site was, a big red circle was noted and it was swollen; I would get hot and cold; I was sweating; Pain in her chest, stomach, back and head; Fatigue; Pain in left elbow; goes to bathroom and bowel was not emptying the way it should; rib cage is going on the side of body noticed this thumping; Her lips were red; Throat was red; Been sick and just laying around; Her eyes were red; Cramp in left arm where site of injection; Sharp pains were hitting her in her eye, thigh, chest, head, and the arm; Sharp pains were hitting her in her eye, thigh, chest, head, and the arm; This is a spontaneous report received from contactable consumer (patient). A 70-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via unspecified route of administration on 15Mar2021 (at the age of 70 years) at a single dose in the left arm for COVID-19 immunization. Medical history included lung issues and allergic asthma. Family history included brothers and sisters who died of lung issues and third sibling sister died many years ago due to allergic asthma. The patient previously took flu vaccine for immunization and experienced severe pain throughout her whole body. On 15Mar2021, patient received the first dose of Pfizer COVID-19 vaccine. Later on, that day when she got home after receiving the vaccine, underneath the arm where the injection site was, a big red circle was noted and it was swollen, beneath this area was a red circle where blood clotted or something, she would get hot and cold and take her clothes off because she was sweating but did not have fever, there was pain in her chest, stomach, back and head, wheezing, shortness of breath, fatigue, swelling of the face, pain in left elbow. She goes to bathroom and bowel was not emptying the way it should. She also noted that her rib cage is going on the side of body noticed this thumping, lips and throat were red. She's been sick and just laying around, her eyes, under her nose and left elbow were red, had cramp in left arm where site of injection, and sharp pains were hitting her in her eye, thigh, chest, head, and the arm. Patient clarified that these symptoms began on 15Mar2021, the same day she received the Pfizer COVID-19 vaccine. On 23Mar2021, patient went to the ER and the findings were lower chest partial atelectasis or scarring in the lung bases bilateral and partial lung collapse (both upper and lower parts collapsed). At the hospital her temperature was 98.9 F on 23Mar2021, but 97.1F - 97.7F is her normal temperature. She went to the Pulmonary doctor also, but was getting a second opinion because she knew it could be life threatening. The pulmonary doctor made light of it saying they were just creases, like creases in pants. Patient said crease was a far cry from partial lung collapse on both bases and the Pulmonary doctor also said that it is in the upper part of the lung also. This scared her and made her think nobody cared. She did not know if she should provide the information because the doctor did not seem to believe that that her symptoms were coming</p>
COVID19 VACCINE	PFIZER\BIONTECH	1224892-1	65+ years	0 days	<p>Pulmonary embolism numerous in both lung happened with 48 of second dose; second dose was administered on 15Mar2021; first dose was administered on 01Mar2021; second dose was administered on 15Mar2021; first dose was administered on 01Mar2021; This is a spontaneous report from a contactable consumer (patient). A 74-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not provided) via an unspecified route of administration on 15Mar2021 as a single dose for COVID-19 immunisation. Medical history included Lupus, glaucoma, hypertension, irritable bowel syndrome (IBS), fibro and allergies to Gluten. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient has not had any vaccine in four weeks but took other medications in two weeks (unspecified). The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 01Mar2021 13:15 for COVID-19 immunization. On 17Mar2021 20:00, the patient experienced Pulmonary embolism numerous in both lung happened with 48 of second dose. The event resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization (Prolongation of existing hospitalization) as the vaccine was received during existing hospitalization, Life threatening illness (immediate risk of death from the event). Treatment was given in response to the event which included bed rest and pain medications. The patient underwent COVID test post vaccination via nasal swab on 24Mar2021 and was negative. The outcome of the event pulmonary embolism was recovering.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1227158-1	60-64 years	0 days	<p>found a deep blood clot.; my calf, foot, and knee swelled up by evening./It stayed swollen for a week; my calf, foot, and knee swelled up by evening./It stayed swollen for a week; This is a spontaneous report from a contactable consumer (patient). A 61-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) (at 61-years of age), dose 1 via an unspecified route of administration, administered in arm right on 17Mar2021 12:00 (Batch/Lot number was not reported) as a single dose for COVID-19 immunisation. Medical history included blood clot after a back fusion about 16 years ago (2005), and had a knee replacement 3 months before the vaccine (Dec2020). The patient's concomitant medications were not reported. The patient previously took ANCEF [cefazolin sodium] and had allergies; and oxacillin which the patient had allergies and hepatitis. The patient was not diagnosed with Covid prior to vaccination nor was he tested for covid since vaccination. The patient did not receive any other vaccine within 4 weeks prior to Covid vaccine. It was reported that the day the patient received the first vaccine his calf, foot, and knee swelled up by evening. It stayed swollen for a week and he went to see his doctor. He did an ultrasound on his calf and found a deep blood clot. He was now on blood thinners. He mentioned that he had a knee replacement 3 months before the vaccine but it was progressing fine. Usually blood clots occur after surgery within a 2 week period. He had a blood clot after a back fusion about 16 years ago. He was reporting this because his doctor was not sure why he got the blood clot and it coincided with the vaccine. The patient underwent lab tests and procedures which included ultrasound scan: found a deep blood clot in Mar2021. The events started on 17Mar2021 18:30 with outcome of recovering. The events resulted to doctor or other healthcare professional office/clinic visit. Therapeutic measures were taken as a result the events with LOVANOX and PRADAXA. Follow-up attempts are completed. No further information is expected.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1227978-1	18-29 years	0 days	<p>Nodule on both forearm; swelling along veins and they became painful; swelling along veins and they became painful; 2 superficial venous thromboses, one in my arm and another in my leg; 2 superficial venous thromboses, one in my arm and another in my leg; Deep vein thrombosis leg; This is a spontaneous report from a contactable consumer (patient). A 23-year-old male patient received the 2nd dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration in arm left on 25Jan2021 (Lot Number: EL3247), as single dose, for COVID-19 immunisation. Patient was vaccinated in the hospital. Medical history and concomitant medications were none. Patient did not have known allergies. Patient did not have COVID-19 prior to vaccination. Previously the patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech, lot# EL0142) on 04Jan2021 at 11:30 AM in left arm and experienced nodule on extremity and vaccination site nodule. The patient experienced deep vein thrombosis leg (medically significant, life threatening) in 2021 with outcome of not recovered, nodule on both forearm (life threatening) on 25Jan2021 with outcome of not recovered, swelling along veins and they became painful (life threatening) in 2021 with outcome of not recovered, swelling along veins and they became painful (life threatening) in 2021 with outcome of not recovered, 2 superficial venous thromboses, one in arm and another in leg (life threatening) in 2021 with outcome of not recovered. It was reported that within hours from second dose the nodules reappeared. At this time, patient was told to take Allegra and did so for 4 weeks. A month later, patient began to see some swelling along his veins and they became painful. This developed into a DVT, deep venous thrombosis, in leg and 2 superficial venous thromboses, one in arm and another in leg. all the events required physician office visit. None of the events occurred at vaccination site, but physician believed they were triggered by receiving the vaccine. Treatment of Eliquis was initiated the day before report. Patient was not tested for COVID-19 post vaccination. Follow-up attempts are completed. No further information is expected.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1235740-1	60-64 years	0 days	I fainted; blood clots; light headed; I lost all color and my skin was wet and clammy; I lost all color and my skin was wet and clammy; This is a spontaneous report from a contactable consumer. A 60-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) lot number: EN6199, via an unspecified route of administration, administered in right arm on 04Mar2021 15:00 as single dose for Covid-19 immunisation. Medical history included known allergies to Atovaquone/proguanil. Concomitant medications were not reported. On 04Mar2021, approximately 10 minutes post vaccine, the patient fainted in the waiting area. She was told by a witness that she fainted two times. EMTs administered an IV and did a simple EKG. The patient lost all color and her skin was wet and clammy. EMTs were concerned about her heart and transported her to the ER where she had a full EKG and lab work for D-Dimer to consider blood clots. The patient has remained lightheaded for weeks after the vaccine. The outcome of the events was recovered with sequelae.
COVID19 VACCINE	PFIZER\BIONTECH	1235743-1	18-29 years	0 days	DVT in my right calf; I felt pain in my calf between 10-20 hours before second vaccine dose. The pain went away but came back 5 hours after second vaccine dose. In the next 10 hours, the pain became severe and constant; I felt pain in my calf between 10-20 hours before second vaccine dose. The pain went away but came back 5 hours after second vaccine dose. In the next 10 hours, the pain became severe and constant; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer (patient) reported that a 28-year-old female patient received second dose of BNT162B2 (Lot Number: ER8734), via an unspecified route of administration, administered in the left arm on 02Apr2021 as a single dose for COVID-19 immunization. The patient previously received first dose of BNT162B2 via an unspecified route of administration, administered in Arm Left on 12Mar2021 (Batch/Lot Number: EP7534) for COVID-19 immunization. Medical history included corneal abrasion and pain in my calf, both from an unknown date and unknown if ongoing. Concomitant medications included tetryzoline hydrochloride (EYE DROPS [TETRYZOLINE HYDROCHLORIDE]) taken for an unspecified indication, start and stop date were not reported. The patient experienced DVT in her right calf on an unspecified date and 'felt pain in my calf between 10-20 hours before second vaccine dose. the pain went away but came back 5 hours after second vaccine dose. in the next 10 hours, the pain became severe and constant' on 02Apr2021. The clinical course was reported as follows: The patient felt pain in her calf between 10-20 hours before second vaccine dose. The pain went away but came back 5 hours after second vaccine dose. In the next 10 hours, the pain became severe and constant. At 40 hours after second vaccine dose, she went to the ER and was diagnosed with a DVT in her right calf. The adverse events result in Emergency room/department or urgent care. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccines within four weeks prior to the vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Therapeutic measures were taken as a result of both events which included blood thinners. The outcome of the events was recovering.
COVID19 VACCINE	PFIZER\BIONTECH	1235767-1	18-29 years	0 days	small clot behind my left knee; left foot had swollen; This is a spontaneous report from a contactable consumer (patient). A 20-year-old female patient received BNT162B2 (lot number: ER2613) first dose on 20Mar2021 10:15 on left arm at single dose for COVID-19 immunisation. Medical history and concomitant medications were none. Patient is not pregnant. No other vaccine in four weeks. No Covid prior vaccination, No known allergies. She took the vaccine around 10:00am and around 6:00pm (also reported as 06:30 PM) she noticed that her left foot had swollen. She consulted with her general physician and he requested that patient did an Ultra Sound exam of her left leg. The result of the exam reported a small clot behind her left knee. Therefore, doctor suggested that she reported these events to Pfizer so an evaluation is made to identify if similar events have occurred with other patients. She was concerned if she should take the second shot on 17Apr2021. AE resulted in Doctor or other healthcare professional office/clinic visit. Patient received Eliquis 5mg (two times daily) as treatment. Patient had Nasal Swab on 01Apr2021 and tested negative. The outcome of the events was not recovered.

COVID19 VACCINE	PFIZER\BIONTECH	1254628-1	65+ years	0 days	<p>Blood and clots came out of nose and mouth, first vaccine.; Blood and clots came out of nose and mouth, first vaccine.; Blood and clots came out of nose and mouth, first vaccine.; Face felt tight, first vaccine.; Mouth and nose dry, first vaccine.; Mouth and nose dry, first vaccine.; Sore arm, first vaccine.; This is a spontaneous report received from a contactable consumer(patient). A 73-year-old female patient received first dose of BNT162b2 (Pfizer-BioNTech COVID-19 Vaccine), at the age of 73-years-old, via an unspecified route of administration, administered in Arm Left (in the back of the arm) on 20Jan2021 (maybe at 11:10 am) (Lot Number: EL3246; Expiration Date: Apr2021) as single dose for covid-19 immunisation. Medical history included ongoing Postural vertigo maybe 10 years ago for a day. No family medical history relevant to AE. The patient's concomitant medications were not reported. Patient got the Shingles vaccine years ago and the next day, she had a sore arm and tingles, up and down her arm. She didn't feel food for 7 days and felt achy. It was the first Shingles shot. No prior Vaccinations (within 4 weeks). The patient experienced blood and clots came out of nose and mouth on 21Jan2021 (the same time that she woke up) with outcome of recovered on 21Jan2021. She blew her nose and leaned over and noticed a drop of blood on the rug and grabbed a Kleenex. She blew her nose, easy, and all of a sudden blood and clots came out of her nose and mouth. It lasted for about 8 minutes. Sore arm on 20Jan2021 (started in the evening) with outcome of recovered on 21Jan2021. Face felt tight on 21Jan2021 (around 8:30 or 9:00 am) with outcome of recovered on 21Jan2021. Mouth and nose dry on 21Jan2021 (in the morning) with outcome of recovered on 21Jan2021.</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1255308-1	40-49 years	0 days	<p>she thought she had a blood clot; maybe it is MS (multiple sclerosis); possible septal infarct; weakness in her left arm; losing her balance; vaccine was given up high on her arm, not 2 fingers down. She thought they had hit bone; less range of movement in her left foot; trouble walking; like someone who had a stroke; numbness; legs felt heavy climbing stairs; immediate pain when needle went all the way in and worse when vaccine went in; pain in shoulder joint; This is a spontaneous report from a contactable consumer (patient). A 49-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: Ep6955), dose 1 via an unspecified route of administration, administered in Arm Left on 25Mar2021 18:00 (at the age of 49years) as single dose for Covid-19 immunization. The patient is not pregnant at the time of vaccination. Medical history included anemia that is treated, living kidney donor, gastric bypass in 1999, gallbladder removal, hysterectomy, intussusception x2, migraines, high heart rate, and smoking. Concomitant medications included omeprazole (OMEPRAZOLE), amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate (ADDERALL), and albuterol [salbutamol] (ALBUTEROL [SALBUTAMOL]); all taken for an unspecified indication, start and stop date were not reported. The patient previously received Flu vaccine and Tetanus vaccine. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient has not been tested for COVID-19 since the vaccination. She got the shot on 25Mar2021 on Thursday evening at 1800. She is 49 years old and has had all the flu shots and tetanus shots. She has never had one hurt so bad. She stated that the vaccine was given up high on her arm, not 2 fingers down. She thought they had hit bone. It was reported that the patient experienced immediate pain when needle went all the way in and worse when vaccine went in. The whole time it hurt really bad and her arm hurt severely for 2 days from 25Mar2021. She still has pain in shoulder joint. That aside wasn't a big deal, it went away even though the joint is sore. The following Monday 29Mar2021 in the evening, her legs felt heavy and she had trouble going up the stairs. Then she had complete numbness of her left leg, from her hip or butt crack to the tip of her toes. It was on the same side she had the shot. It was further reported that the patient's legs felt heavy climbing stairs then she woke Thursday morning with her left leg numb. She couldn't feel herself starting to have a bowel movement because the numbness went all the way up to that area. She went to the ER (emergency room) on Saturday night (03Apr2021) because she was afraid of a blood clot. An ultrasound was done on her left leg, CT of head and neck, and blood work with nothing found. She has numbness and less range of movement in her left foot with trouble walking and have had no improvement with calf being numb. It was further clarified that when she was Easter shopping, there was numbness in her foot was causing her to drag her foot around the store. It was like someone who had a stroke, with slight impairment on one side. Her foot slaps the floor. She doesn't have control of it, she can't flex her foot up and down at all and she has little movement in her toes, even now. When she went to the emergency room, she thought she had a blood clot. She is a kidney donor and is healthy over all except for anemia that gives her tingling toes since she was 30, off and on. She never had a body part felt so numb, other than when she sits on her leg wrong. They did a bunch of tests there. They did a doppler, CT scan, and an EKG (unspecified date)</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1255642-1	65+ years	0 days	<p>Blood clots in Lungs; No longer able to do activities of daily living; Almost fell to floor from sitting position; short of breath; total body exhaustion/fatigue; sleepy throughout the day; unstable, weak; debilitating symptoms bedridden/unstable, weak; debilitating symptoms bedridden; passed out completely while sitting; Unable to complete daily 1 mile walk at park/Unable to take stairs; Lightheaded/dizzy; This is a spontaneous report from a contactable consumer. A 78-years-old female patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration, administered in Arm Right on 26Mar2021 15:00 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. Medical history included patient had COVID-19 Dec2021 and recovered completely in 2 weeks. Symptoms: fever, sleepy. Went back to daily walk after 2 weeks. No loss of smell, no loss of taste, no mental changes- was very happy with my complete recovery. Took vaccine 26Mar2021 at recommendation of doctor to be safe from variants. Regret deeply, still hospitalized as of this writing. Concomitant medications included ramipril; rosuvastatin calcium 40mg; levothyroxine, all taken for an unspecified indication, start and stop date were not reported. The patient previously took sulphur and experienced allergies. The patient experienced unable to complete daily 1 mile walk at park/unable to take stairs on 27Mar2021, lightheaded/dizzy on 27Mar2021, passed out completely while sitting on 28Mar2021, unstable, weak on 30Mar2021, short of breath on 31Mar2021, total body exhaustion/fatigue on 31Mar2021, sleepy throughout the day on 31Mar2021, almost fell to floor from sitting position on 09Apr2021, debilitating symptoms bedridden/unstable, weak on 26Mar2021, debilitating symptoms bedridden on 26Mar2021, no longer able to do activities of daily living on 13Apr2021, blood clots in lungs on 14Apr2021, all with outcome of not recovered. Reported adverse event: 27Mar2021 - Unable to complete daily 1 mile walk at park. Lightheaded, dizzy 28Mar2021 Dizzy, passed out completely while sitting. Revived and taken to hospital by ambulance 28Mar2021 Admitted to (hospital name withheld) 30Mar2021 Discharge from hospital - unstable, weak 31Mar- 08Apr2021 - short of breath easily. Unable to take stairs. Discontinued daily walk, weak, total body exhaustion, sleepy throughout the day 09Apr2021 - Almost fell to floor from sitting position. Patient's daughter lowered patient gently to the floor. Revived shortly 13Apr2021 Saw primary doctor Dr (name withheld). Shared her debilitating symptoms bedridden since Covid-19 vaccine on 26Mar. BP taken from lying down, sitting and standing was markedly different and explained caused passing out and lightheaded. No longer able to do activities of daily living 14Apr2021 - Exhaustion and fatigue, her daughter to her back to the hospital 14Apr2021 - Passed out in Emergency Room @ (hospital name withheld). Admitted. Blood clots in LUNGS. The events resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event), Disability or permanent damage. The patient was hospitalized for unable to complete daily 1 mile walk at park/unable to take stairs, lightheaded/dizzy, passed out completely while sitting, all from 28Mar2021 to 30Mar2021. The patient underwent lab tests which included blood pressure measurement: markedly different on unknown date. Patient was not pregnant. No other vaccine in four weeks. Patient had covid prior vaccination. No covid tested post vaccination. The</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1261710-1	50-59 years	0 days	<p>to make sure there is no pulmonary embolism; Shaking legs and arms; Lightheaded; PVCs (Ventricular premature beat); Large black bruise on left breast; 40 hrs fever; throwing up/vomiting; nausea 36 hours; intermittent breathing issues/sporadic breathing issues/difficulty breathing and hard to get a breath; She was weak; severe migraine; Headache; Brain fog; This is a spontaneous report from a contactable consumer (patient). A 59-year-old female patient received second dose of bnt162b2 (BNT162B2, lot number ER8727, expiration date: 31Jul2021), via an unspecified route of administration in arm left on 07Apr2021 12:00 as single dose for Covid-19 immunisation. Medical history included allergy ( macro Danton, sulfā). Patient was not pregnant at time of vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient's concomitant medication included Nerontin. The patient reviously received flu vaccine and had normal things, previously received first dose of bnt162b2 (Lot Number: EN5318; Expiration Date: 31May2021) in arm left on 17Mar2021 16:00 and experienced acute lymphatic response, brain fog and arm started to hurt. The pateint was calling because her doctor, who she saw yesterday 14Apr2021, told her she should let Pfizer know what was going on. She had a reaction to the Pfizer Covid19 Vaccine. she was now having PVCs. The patient added that all of the events started with a fever, and throwing up. She had a fever and threw up for 36 hours. She had to contact her physician to get medication and to stop vomiting and the nausea and everything. During that time, she was sick. She was having intermittent breathing issues which she did not think she felt too much of until after the other sickness was over. She was weak, like people get after they are sick, and had bizarre shaking legs and arms which was strange. She added that she had breathing issues and difficulty breathing and hard to get a breath. That was what she was dealing with. Treatment: caller took Pedalyte and all the proper things to get back into better shape. The breathing issue still remained. The doctor called in a rescue inhaler. She kept going downhill so he called in a rescue inhaler. Large black bruise on left breast after second vaccine: Caller added that this one will not be believed but on Monday, she woke up and got dressed again and was just weak and had breathing issues but was just doing work on the laptop. She did not fall, she did not run into anything. In the evening, she went to take a bath and saw that when she took her clothes off there was a large black bruise on her left breast, it was probably 2 inches in diameter. It is very large, but does not hurt like a bruise. She checked the rest of her body for blood issues and only saw a couple normal looking bruises. She contacted her doctor, and they questioned her thoroughly on her bruising and activity. This was on Monday. Tuesday, she still felt the same headache, weak, and breathing issues. PVCs (Ventricular premature beat) after second vaccine: Yesterday, 14Apr2021, she started declining and the doctor wanted to see her. Caller stated the doctor heard PVCs in her heart. Caller asked clarification of PVC abbreviation and does not provide. She never had heart issues ever. The doctor did blood work and a chest x-ray, and saw the bruise and was worried about her blood. Caller added that even though these are not listed as side effects of the vaccine, she was worried. Her doctor sent her to a facility for chest x-rays to make sure there is no pulmonary embolism. Caller confirmed this was on 14Apr2021. She has not yet heard back. PVCs after second vaccine: Caller added the doctor said her lungs</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1261717-1	50-59 years	0 days	<p>portal vein thrombosis; ischemic colitis; This is a spontaneous report from a contactable consumer (patient). A 51-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection; Batch/Lot number was not reported), via an unspecified route of administration, administered in the left arm, on 07Apr2021 at 09:30 AM at the age of 51-years-old as single dose for COVID-19 immunization. The vaccination facility type was pharmacy or drug store. The patient was not pregnant. The patient had no other vaccine in four weeks. The patient had no medical history and had no known allergies. Concomitant medications included estradiol patch and cyanocobalamin (VIT B12); both taken for unspecified indications, start and stop dates were not reported (reported as other medications in two weeks). The patient previously received the first dose of BNT162B2, administered in the left arm on 10Mar2021 at 08:45 AM at the age of 51-years-old for COVID-19 immunization. The patient reported that at 11:30 pm on 07Apr2021, she had extreme, spontaneous, stomach cramps that was so bad she thought she was going to pass out. That lasted for one hour, then diarrhea. A few hours later, she started blood red rectal bleeding. At the hospital (on Apr2021), she was diagnosed with Ischemic colitis (from colonoscopy) and a blood clot was also found, portal vein thrombosis. She was 100% certain the extreme stomach cramps were brought on by the vaccine and that in turn caused the ischemic colitis; the blood clot may or may not have already been there. The patient reported that the doctors at the hospital were quite put off to try to tie any relation to this episode with the vaccine which was quite frustrating to the patient as it was quite obvious (as reported). The events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, and hospitalization. The patient was hospitalized for 2 days in Apr2021. On treatment for the events, the patient reported that the colitis healed on its own, and she was on blood thinners. The patient had no COVID prior the vaccination. The patient was test for COVID post vaccination which was a nasal swab with a negative result on 08Apr2021. The outcome of the events was recovering. Information on the lot/batch number has been requested.</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1261794-1	60-64 years	0 days	<p>had a stroke after getting the Pfizer vaccine; weakness left arm and left leg; Headache; Dural venous sinus thrombosis; This is a spontaneous report from a contactable consumer (patient). A 62-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) (at 62-years of age) dose 2 via an unspecified route of administration, administered in arm right on 01Apr2021 10:20 (Batch/Lot number was not reported) as a single dose for covid-19 immunisation (to not get Covid). Medical history included ongoing multiple sclerosis which was diagnosed back in the early 90's and the doctors saw no new reasons on any part of the MRI of the brain, neck, and spine, there were no new lesion and she has had no problems for 30 years; and she had sinus pressure. There were no concomitant medications. Historical vaccine included BNT162B2 (Batch/lot number: EN6208) dose 1 in her left arm on 11Mar2021 (at 61 years of age) for COVID-19 immunisation. It was reported that the patient had a stroke after getting the Pfizer vaccine. She stated that she was in the ICU for 3 days. They tested every part of her body and couldn't find a reason. She added that she had a dot in her brain with a small bleed and they told her it was highly unusual to happen in that part of the brain. It was stated that it was where the blood goes from the brain to the heart. She mentioned that it was a dural venous sinus thrombosis. She was in the neuroscience ICU for 3 days and her left leg and left arm are still weak and she will start PT. She wanted to talk about reporting and let us know this was happening and that the neuroscience team reported it to the CDC online while she was in the hospital. She wanted to talk about her concerns and see if we are seeing this with other people. She added that she was tested, and they found nothing. She mentioned that she got the vaccine in a Thursday morning and by Friday she had weakness in her left arm and left leg and a headache. She added that there was a high probability that it was related, that it was a new vaccine and it was hard to say it definitely happened from that but it was a high probability. She had other questions, she has heard from other people with other vaccines and people with Covid experience blood clots. She stated that she was wondering what if it was with the vaccine that is reacting to what it thinks is Covid, or is it the body's response. She was wondering if Pfizer comes out with a booster with the variant, should she not take the booster. She stated that it could have killed her if they had not caught the blood clot in her brain and had she not gone to the ER it could have killed her and she was concerned about taking a booster. She provided that she had the Pfizer vaccine on 01Apr2021 in the morning and had a headache that same day and who knows when on Friday morning she had weakness in her left leg and left arm, so within 24 hours. She provided that she went to the ER Saturday 03Apr2021, that she wasn't sure about it and you don't go running for everything. Stated she was admitted 03Apr2021 and was discharged 05Apr2021 or 06Apr2021. She clarified that her headache was totally gone, that she had sinus pressure that was not related and had it as a constant in her life, it was normal for her and happens with changes with the weather. The patient was hospitalized for had a stroke after getting the pfizer vaccine (cerebrovascular accident) from 03Apr2021 to 06Apr2021. The patient underwent lab tests and procedures which included blood work constantly, CAT scan of her torso, several CAT scans of her brain, had MRI's and CAT scans constantly, brain MRI, MRV of the brain all on an unknown date with unknown results. The events</p>
COVID19 VACCINE	PFIZER\BIONTECH	1261801-1	30-39 years	0 days	<p>Heavy menstrual bleeding with clots; Heavy menstrual bleeding with clots; This is a spontaneous report from a contactable nurse (patient). A 33-year-old female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiration date unspecified), via an unspecified route of administration, administered in left arm on 08Apr2021 13:00 as single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient was not pregnant and had no other vaccine in 4 weeks. On 08Apr2021 13:30, the patient experienced heavy menstrual bleeding with clots. There was no therapy for the events. The patient had no COVID prior vaccination and was not COVID tested post vaccination. Outcome of events was recovered on an unspecified date. Information about Lot/Batch number is requested.; Sender's Comments: Based on the available information the reported events were attributed to an underlying or an intercurrent medical condition and it is assessed as unrelated to the suspect drug bnt162b2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1261831-1	65+ years	0 days	Blood Clots both legs; had other vaccine same date at 2nd dose in the left arm; had other vaccine same date at 2nd dose in the left arm; This is a spontaneous report from a contactable Consumer (patient). A 69-year-old male patient received the 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9269) via an unspecified route of administration in the left arm on 15Apr2021 12:00 PM at single dose for COVID-19 immunization. Medical history was unknown. The patient had no known allergies. The patient had no covid prior vaccination, no covid tested post vaccination. The patient had no other vaccine in four weeks or other medications in two weeks. Concomitant medications were none. The patient had other vaccine same date at 2nd dose in the left arm. The patient experienced blood clots both legs on 15Apr2021 12:15 PM. The patient had extensive dvt IVC and both legs as treatment for event. Outcome of the event blood clots both legs was not recovered. AE resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization (duration: 5 days), Life threatening illness (immediate risk of death from the event).
COVID19 VACCINE	PFIZER\BIONTECH	1265986-1	60-64 years	0 days	Doppler showed a blood clot; Pain behind her cast; Really bad case of diarrhea; Swelling in her knee; Leg was swelling/right shoe was tight; Lower extremity venous ultrasound right calf vein acute deep vein thrombosis of the right lower extremity involving the popliteal vein; It was tender on her right leg on the left side of the tibia/It is very tender to the touch; Red mark on her leg with a little nodule; Red mark on her leg with a little nodule; Calf pain; This is a spontaneous report from a contactable consumer. A 62-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EP7533; Expiration date was not reported) on the right arm on 30Mar2021 as a single dose, with route of administration unspecified, for COVID-19 immunization at the clinic. Medical history included pain and headache. Concomitant medications included paracetamol (TYLENOL ARTHRITIS) for pain; hydrocodone for pain; amitriptyline for headache; and ongoing paracetamol (TYLENOL EXTRA-STRENGTH) for pain. The patient had previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EN6208; Expiration date was not reported) on the right arm on 11Mar2021 (when the patient was 62 years old) for COVID-19 immunization. On 07Apr2021, the patient's doppler showed a blood clot. On 30Mar2021, the patient had a really bad case of diarrhea; swelling in her knee; and leg was swelling/right shoe was tight. On 02Apr2021, the patient had pain behind her cast. On an unspecified date in 2021, the patient's lower extremity venous ultrasound showed right calf vein acute deep vein thrombosis of the right lower extremity involving the popliteal vein; was tender on the right leg on the left side of the tibia that was very tender to the touch; had a red mark on her leg with a little nodule; and had calf pain. The events had resulted into an emergency room visit and physician's office visit. The patient had received treatment for the events, 'blood clot', 'lower extremity venous ultrasound right calf vein acute deep vein thrombosis of the right lower extremity involving the popliteal vein', 'leg was swelling/right shoe was tight', 'pain behind her cast' and 'tender on her right leg on the left side of the tibia that was very tender to the touch'. The outcome of the events was recovered on 30Mar2021 for 'really bad case of diarrhea'; was recovering for 'leg was swelling/right shoe was tight', 'pain behind her cast' and 'red mark on her leg with a little nodule'; and was unknown for all the other events.

COVID19 VACCINE	PFIZER\BIONTECH	1266022-1	30-39 years	0 days	<p>Blood clots; headache; nervousness; anxiety; This is a spontaneous report from a non-contactable consumer (patient). A 34-year-old female patient not pregnant received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Left on 03Apr2021 09:00 (Lot Number: ER8733) as single dose (at the age of 34-years-old) for covid-19 immunisation. Medical history included allergies (known allergies: yes). Concomitant medications in two weeks prior to the vaccination included vitamin B complex (B-COMPLEX), magnesium (MAGNESIUM), chlorophyll (CHLOROPHYLL), vitamin D NOS (VITAMIN D NOS). Patient did not receive other vaccine in four weeks prior to the COVID vaccine. It was unknown if patient had COVID prior vaccination. Patient was not tested for Covid post vaccination. On 03Apr2021 patient experienced blood clots, headache, nervousness and anxiety. Events resulted in Doctor or other healthcare professional office/clinic visit. No treatment was required. Outcome of the events was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the available information, the known safety profile and the temporal association of BNT162B2 administration to the event of Thrombosis, a possible contribution of the drug to the event cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1269505-1	Unknown	0 days	<p>asked if this was a blood clot; a big black spot next to her knee, and if she touched it, it hurt; a big black spot next to her knee, and if she touched it, it hurt; This is a spontaneous report from a contactable consumer (patient). A (age: 70; unit: unspecified) female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; solution for injection) via an unspecified route of administration on 12Apr2021 as a single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. On 12Apr2021 the patient experienced a big black spot next to her knee, and if she touched it, it hurt. The patient called to report that she received the first dose of the COVID-19 vaccine yesterday 12Apr2021 and she was supposed to receive the second dose on 03May2021. When she got home yesterday afternoon, she ended up with a big black spot next to her knee, and if she touched it, it hurt. It was a little larger than a quarter coin, about the size of a silver dollar. She stated it was next to the inner part of her knee. The patient asked if this was a blood clot. She stated that she was worried with all the information about blood clots and the COVID-19 vaccines. She stated that she did not know if it was a blood clot but asked if it was a blood clot. The clinical outcomes of the events a big black spot next to her knee, and if she touched it, it hurt were both unknown. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1269527-1	60-64 years	0 days	<p>multiple pulmonary embolisms/Pulmonary embolism and subsegmental pulmonary embolus; felt sluggish directly; feeling discomfort in my lungs; pain in my lung/chest area; pain in my lung/chest area/right-sided chest pain under the rib; difficult and extremely painful to breathe/significant shortness of breath/shortness of breath due to extreme pain; blood clots; This is a spontaneous report from a contactable consumer (patient) and physician. A 60-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EP7534 and expiration date not provided), via an unspecified route of administration, administered in Arm Left second dose on 07Apr2021 17:00 at single dose for covid-19 immunisation. The patient medical history was not reported. The patient was not pregnant at time of vaccination. The patient's concomitant medications included cetirizine, diphenhydramine, and phenylephrine. The patient historical vaccine includes bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EN6203), right arm first dose on 10Mar2021 for COVID-19 Immunization. On 07Apr2021 21:30, the patient felt sluggish directly after receiving the second dose. The patient began feeling discomfort in my lungs about 5 hours after the dose. The pain in my lung/chest area grew worse throughout the night to the point where it was difficult and extremely painful to breathe. The patient went to urgent care in the morning, and they ran an EKG, urine analysis, and chest X-ray: all with unknown results. They were concerned it could be something worse along with potential pneumonia, so they sent me to the emergency room. In the emergency room, I received a CT scan where they found multiple pulmonary embolisms (1 large one in my right and multiple in my left lung). The patient stated that she had just had my yearly physical the previous week (Apr2021), with no signs of any health issues. With that, the doctors believed my condition to be related to my 2nd dose, so I was admitted to the hospital. I had to stayed for 2 nights. I am now on blood thinners, other meds (pain medications), and require oxygen during sleep (O2 levels drop too low). I have been referred to lung and hematology specialists. Also, reported that patient experiencing significant shortness of breath and right-sided chest pain under the rib. This persisted for some time until she presented to the emergency department found to have segmental and subsegmental pulmonary embolus. Additionally, the patient experienced blood clots, chest pain, and shortness of breath due to extreme pain. Hypercoagulable work-up pending. The patient underwent lab tests and procedures which included COVID-19 virus test (nasal swab) with result of negative. The outcome of the events was recovering.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported events occurred in a plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified.</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1269533-1	50-59 years	0 days	<p>he reports discoloration resolved but developed worsening bilateral lower extremity edema; lower extremity pain and swelling; lower extremity pain and swelling; blue toes on both feet; extensive deep vein thrombosis in left lower extremity requiring treatment and thrombectomy; legs were cool to touch; This is a spontaneous report from a contactable physician reporting for a patient. A 51-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 intramuscular on 02Apr2021 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation, at 51 years old. Medical history included triplegia, neurogenic bladder, hyperlipidaemia, chronic abdominal pain, type 2 diabetes mellitus, chronic opioid use, known allergies: Latex from an unknown date and unknown if ongoing. No other vaccine in four weeks. No COVID prior vaccination and was not tested for COVID post vaccination. The patient's concomitant medications were not reported. The patient previously took sulfamethoxazole;trimethoprim and experienced allergies to Sulfamethoxazole-trimethoprim. The patient experienced lower extremity pain and swelling, lower extremity pain and swelling, blue toes on both feet, extensive deep vein thrombosis in left lower extremity requiring treatment and thrombectomy, legs were cool to touch on 02Apr2021; and he reported discoloration resolved but developed worsening bilateral lower extremity edema on an unspecified date. Clinical course was reported as follows: The patient presented to the hospital on ""4/7"" (as reported) with lower extremity pain and swelling. Patient reports received 1st dose on pfizer vaccine on 4/2 (as reported) and immediately noticed blue toes on both feet and legs were cool to touch. He reports discoloration resolved but developed worsening bilateral lower extremity edema. Imaging revealed extensive deep vein thrombosis in left lower extremity requiring treatment and thrombectomy. The patient underwent lab tests and procedures which included sars-cov-2 antibody test: negative on 07Apr2021, and sars-cov-2 antibody test (nasal swab): negative on 13Apr2021. Treatment was received for the events. The events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization (Apr2021). Outcome of the events was recovering. Information on the lot number has been requested.""</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1269535-1	50-59 years	0 days	<p>blood clot under her eye; bright red bruise in the corner of the eye to the middle of the eye underneath; feeling crummy; she was down; headaches; couldn't move; arm hurt all the way below her arm pit into her breast; arm hurt all the way below her arm pit into her breast; arm hurt all the way below her arm pit into her breast; got very sick; This is a spontaneous report from a contactable consumer (patient). A 59-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: ER8737), dose 1 via an unspecified route of administration, administered in Arm Left on 05Apr2021 08:30 (at the age of 59years) as single dose for Covid-19 immunization. Medical history included ongoing rheumatoid arthritis and osteoarthritis (not bad enough that she takes treatment, but she is diagnosed; she was diagnosed way back in 2006). Concomitant products: patient stated she takes some medications (not further specified). The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient reported that she had her first dose of the Pfizer Covid-19 vaccine on 05Apr2021 and got very sick. She was down for two days and after day 10 (as reported) she has a blood clot under her eye. She would like to know what would happen if does not get a second dose. She consulted if there is any talk on whether or not people should receive an additional dose of the Pfizer Covid-19 vaccine next year. The patient further reported that on 06Apr2021 she woke up feeling crummy right away and a couple of hours into that day she couldn't lift her arm, literally couldn't lift arm for 6 inches and stated it went on for 2 days. She further stated that her arm hurt all the way below her arm pit into her breast. She stated that it all ended on 08Apr2021 and she went back to work on 08Apr2021. The patient added that she was down for two days, had headaches, and stated she never knew what people meant when they said they got hit by train. She doesn't believe she had a fever and couldn't move. The patient further stated that she got pretty darn sick and this morning 14Apr2021, she woke up with a blood clot under her eye. She is an esthetician and is pretty good with skin. She stated that she doesn't know how she could get this overnight unless she injured herself in her sleep, but she is a light sleeper. She does not know if it is a dot. She also stated that she called a medical esthetician who told her to take a baby aspirin and cold compress. The patient clarified that she didn't feel so good and today she feels better. She doesn't know that it is a blood clot, it is not raised and not hard, it looks like she has a bright red bruise in the corner of the eye to the middle of the eye underneath, not in the eye. She wants to make it clear she doesn't know if it is a blood clot. She feels like if she hurt herself, that would be the reason, but it would be painful, and it is not. She added that the bruise is about the same. Therapeutic measures were taken as a result of the events (except for feeling down and couldn't move). The outcome of events thrombosis and contusion was not recovered; the outcome of other events was recovered on 08Apr2021.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1269733-1	50-59 years	0 days	<p>blood clot; swelling and pain in right leg; swelling and pain in right leg; right arm hurting tremendously; This is a spontaneous report from a contactable Nurse. A 52-years-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Right on 01Apr2021 13:45; at the age of 52-years-old, (Batch/Lot Number: ER8734) as SINGLE DOSE for covid-19 immunisation. Medical history included ongoing hypertension, ongoing memory impairment (She states that she was diagnosed either last year or the year before that she can't remember. She states that it is ongoing, but it is well controlled). Historical vaccine included vaccine to tetanus (About 3 or 4 years ago). There were no concomitant medications. The patient experienced blood clot (thrombosis) (disability) on 13Apr2021 with outcome of not recovered, swelling and pain in right leg (disability, medically significant) on 09Apr2021 with outcome of not recovered, right arm hurting tremendously (disability) on 01Apr2021 with outcome of recovered on 04Apr2021. The patient underwent lab tests and procedures which included ultrasound scan: positive on 13Apr2021 had a blood clot. Therapeutic measures were taken as a result of blood clot (thrombosis) included Xarelto and due to pain in extremity the patient received ibuprofen (7 ibuprofen every day); Sender's Comments: Based on the information available and a close temporal association, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported events of Thrombosis. The case will be reassessed once new information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1269746-1	40-49 years	0 days	<p>Regular pain feeling; Headache; Muscle pain; Calf feels tight, stiff, it feels like dead weight; Calf feels tight, stiff, it feels like dead weight; Pain running up the right arm up to the shoulder/Calf pain; He asked if someone can tell him if it is a blood clot in the back of his calf; This is a spontaneous report from a contactable consumer (patient). A 46-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in left arm (shoulder) on 12Mar2021 10:07 (Lot Number: EN6202) as single dose for covid-19 immunization. There were no medical history and concomitant medications. The patient has no prior vaccinations within 4 weeks. The patient was not sick at time of vaccination. The patient reported that on 12Mar2021, he has been feeling the regular pain feeling, a headache, muscle pain before, it comes and goes. However, he said that the last few days (2021), there had been, by his calf muscle in the back there, they've been tightening, like stiffening up on him when he's sleeping. His calf feels tight, stiff, it feels like dead weight. It wakes him up at times. He also reported pain running up the right arm up to the shoulder on unknown date in 2021. He was just curious in terms of what that might be. He asked if someone can tell him if it is a blood clot in the back of his calf. The headache went away after 2-3 days. He also reported that his eyes also hurt a little bit and was the same time frame as the headache (onset date reported as 12Apr2021: after the second dose, pending clarification). He stated that those things were just mild, nothing major. He did not take anything for these. He confirmed he no longer had muscle pain. He just has pain behind the calf and right arm up to his shoulder. His calf pain, started to feel tight, started within the last 2- 3 weeks (2021). The arm pain in right arm up to shoulder started maybe within 2 days. The patient received the second dose on 02Apr2021. Outcome of the events muscle pain and headache was recovered in Mar2021, events pain running up the right arm up to the shoulder/Calf pain was not recovered, and outcome of other events was unknown.</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1278527-1	40-49 years	0 days	<p>problem with her cholesterol; pain on the top of my head and my hands hurt/headache; pain on the top of my head and my hands hurt; Nauseous; my hands and feet started going numb; they itch they burn; feet are painful; uncomfortable; blood clot/a clot or something in her legs; from the knees down I was having a lot pain/leg pain felt like it is really deep in the vein; she thought she was having a stroke; cramps; burning from my calf to my feet; pain in her neck then to her back; pain in her neck then to her back; different temperatures like hot and cold make it bad and irritating; can't sleep well because of her symptoms; Swelling in her Feet; can't think right; This is a spontaneous report from a contactable consumer. A 43-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration in the right arm in the morning of 01Apr2021 (Batch/Lot Number: ER8727) as a single dose for COVID-19 immunization. Medical history included ongoing complex regional pain syndrome, ongoing fibromyalgia, ongoing arthritis - all diagnosed 20 years ago. Her mother has lupus and rheumatoid arthritis and she can't have the vaccine, states she doesn't know if something could be genetic. Low potassium in the past and stated that she has a lot of allergies to medications, but she consulted with the pharmacist and he said it would be okay. There were no concomitant medications. No additional vaccine was administered on the same date of BNT162B2 and no prior vaccination within four weeks. The patient was having weird symptoms and she tried looking online and in different groups to find out if anyone has similar symptoms, but she hasn't been able to find anything. She began by saying she has health issues; she has Fibromyalgia and Complex Regional Pain Syndrome. She doesn't know if studies were performed on patients with those disorders that took the vaccine. It's been about 3 weeks since getting the vaccine (Apr2021) and she started having symptoms that she thought could be a blood clot. From the knees down, she was having a lot of pain, cramps, burning from her calf to her feet. She would keep rubbing them and massaging them. It was excruciating pain. She was having symptoms and she did go see her Nurse Practitioner on 14Apr2021 because she thought she was having a stroke or a clot or something in her legs or that she was having a problem with her cholesterol. The nurse thought maybe it was her electrolytes, because she had low potassium in the past, but everything came back normal. Her feet were painful but not as bad in Apr2021. She felt like her condition but it's flaring up like 200% it's like over a 10 on the pain scale. She can't think right, she can't work, and was very uncomfortable in Apr2021. The leg pain felt like it is really deep in the vein, it doesn't feel like it is superficial, and she can feel stuff or liquid flowing. Her pain alternates from her head to her neck to her feet and it is very uncomfortable. Her hands and feet started to go numb, not completely numb but like when they fall asleep from sitting on them and then hit something and it hurts. Her arms were burning like crazy; they itch, they burn in Apr2021. Different temperatures like hot and cold make it painful, bad and irritating, and she can't sleep well because of her symptoms. She doesn't know the exact dates, but it has been about a week, but it is changing. It started with cramps in her legs from her knees down. That is where she had injuries and she thought it was her cholesterol. From her knees down, she has cramps and pain and it is very uncomfortable, she felt a really deep pain. She has pain in</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1278543-1	50-59 years	0 days	<p>swollen joints; her back condition and may have ""pinched a nerve or something; describes it as the worst pain; the leg pain that she is experiencing and would like to know if it is possible that it could be related to a blood clot; leg pain; also has some tingling on the skin; It feels like a Charley's horse; had a horrible flu; Her every muscles and every joint hurt, and her head hurt; Fever; body aches; chills; joint pain; Her every muscles and every joint hurt, and her head hurt; This is a spontaneous report from a contactable consumer (patient). A 53-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in left arm on 07Apr2021 at 14:00 (Batch/Lot number was not unknown; Expiration Date: 31Jul2021), at age of 53 year-old, as 0.3 mL single, for Covid-19 immunisation. Medical history included liver disease from 2016 and ongoing. There were no concomitant medications. The patient previously took the first dose on 17Mar2021 for Covid-19 immunization and experienced fever. The patient received her second dose of the Pfizer BioNTech COVID-19 vaccine on 07Apr2021 and reports having side effects after. She is specifically worried about the leg pain that she is experiencing and would like to know if it is possible that it could be related to a blood clot and if she needs to be worried about it. She stated that with the ""swollen joints"" and everything from the vaccine, it is possible that it worsened her back condition and may have ""pinched a nerve or something."" She describes it as the worst pain she's ever felt in her life and states it ""comes out of the blue"" so she does not have time to prepare for it. She likens it to a ""Charley horse"" but a ""really bad one"" that goes away and has no pain afterwards. She states she is scheduled for an MRI next week of her lower back to investigate. The patient also mentions that she thinks she had COVID-19 at the time of her vaccine because ""when I got the shot, I had a super strong response."" On 07Apr2021, the patient had body aches, chills, she was on the couch for quite a while. The joint pain was incredible, even in her toes. She felt like she had a horrible flu. Her every muscles and every joint hurt, and her head hurt. She was on the couch for like 4 days. On day 3 or 4 she developed intermittent pain in the leg and shin on 08Apr2021. It feels like someone is drilling a jackhammer in it. It feels like a Charley's horse, but not, more like it's in the bone. She didn't associate it with the vaccine at first, even though she had never had this pain before until she got the vaccine. She said that she has had some back problems and scheduled a MRI to see if she had pinched nerve or something. On 08Apr2021, she also has some tingling on the skin. She read about side effects of blood clots and doesn't know if this leg pain could be related to a blood clot. She assumed it could be from her back. She read that with blood clots there is usually an ache and discoloration, which she does not have now. She also read that intermittent Charley's horse could have something to do with blood clots. She has pins and needles on the skin. She also had a headache after the vaccine, but she does not have it now. She said that the pain in her leg that shoots on and bangs in her tibia hurts when bending over, lifting her leg to her chest, squatting to pick up something, and going up and down the stairs. She said that the pain is horrible and it is worse than leg pain, it is worse than a charley horse, it is the worst pain she has ever felt in her life. She cannot stop screaming when it happens. States with the joint pain that she had, there may be a nerve that's being pressed on her back. She said that with all of the information</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1284855-1	40-49 years	0 days	<p>DVT left lower extremity; Bilateral Pulmonary Emboli; first dose: 23Feb2021; second dose: 16Mar2021; first dose: 23Feb2021; second dose: 16Mar2021; This is a spontaneous report from a contactable nurse (patient). A 49-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6199 and expiration date not provided) intramuscular, administered in the left arm on 16Mar2021 13:30 as a single dose for COVID-19 immunization. The patient has no relevant medical history. Family history included diabetes (mother). The patient's concomitant medications were not reported. The patient did not receive any other vaccine within 4 weeks prior to the COVID vaccine. The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6200 and expiration date not provided) Injected intramuscularly in left upper arm on 23Feb2021, 13:30 for COVID-19 immunization and experienced DVT symptoms, soft tissue injury, muscle pull and ankle strain. The patient experienced DVT left lower extremity and bilateral pulmonary emboli on 23Apr2021. The patient called regarding the Pfizer COVID vaccine. He had adverse events to report. He has a DVT on his left calf, which he later clarified was left lower extremity. He is currently on double dose of apixaban (ELIQUIS) since Friday. He finally went and got it looked at. He is still being treated and will be seeing a hematologist. He stated that DVT symptoms occurred after first dose and was undiagnosed. He treated it as soft tissue injury and thought it was a muscle pull and ankle strain. Eliquis was started on 23Apr2021 and dose is 5 mg. He is taking two tablets twice daily for 7 days and then 1, 5mg tablet bid (twice a day) as well. No emergency room or physician's office required but Urgent care facility was visited on 23Apr2021. During this visit, they did Lab work, D Dimer results 1590 on 23Apr2021; Venous Doppler resulted in positive DVT in Left Lower Extremity. Chest CT resulted in positive peripheral defects in small branches of the lower lobes bilaterally, left greater than right, consistent with Pulmonary Emboli. Left sided pleural effusion and left basillary infiltrate, possibly atelectasis or developing infarct. Few pleural based nodular densities at right lung base, again atelectasis versus developing infarcts. The rest just states what was normal. Eliquis was prescribed on 23Apr2021, 5 mg two tablets twice daily for 7 days, then regular dose times 7 days. He is to report to hematologist on 29Apr2021. The outcome of the events deep vein thrombosis and pulmonary embolism was unknown. The reporter assessed the events as serious (life-threatening).; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events DVT of legs and Pulmonary embolism cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1288355-1	65+ years	0 days	<p>Blood clot in lungs and leg; Trouble breathing/Shortness of breath, but not as bad; didn't feel right; Chest tightness; Slightly ill; Sore arm, in left arm where the shot was; Slightly tired; This is a spontaneous report from a contactable consumer. An 81-year-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in the left arm on 10Feb2021 (Batch/Lot Number: EN6201) as SINGLE DOSE for covid-19 immunization. Medical history included Type 2 Diabetes from 2004 and ongoing, High Blood Pressure from 2000 and ongoing (reporter stated she was 81; it's not very high, usually when she goes to the doctor). Concomitant medications not specified but reporter mentioned that everything she has been on she has been on long time; she takes blood pressure medication because sometimes it is high. She has not had started any new medication prior to starting vaccines or during both vaccines. The patient previously received flu shot (September). The patient received her first vaccine dose of bnt162b2 (Lot # EL9262, Expiry date UNKNOWN), on 20Jan2021, at 1:30-1:45, in the left arm and experienced sore arm and slightly tired. The reporter stated that after her second vaccine on 10Feb2021, she had a sore arm, (left, where shot was) and was slightly tired from 10Feb2021 until 12Feb2021. She confirmed she noticed this started the same day, 10Feb2021. On 31Mar2021, she felt slightly ill and had some slightly trouble breathing. She saw her doctor who did some tests. The next day 01Apr2021, her tests came back and the doctor told her to go to the hospital. While in the emergency room she had a CT of the lungs that showed blood clots in both lungs. She was admitted to the hospital where on 02Apr2021 they did a ultrasound of her legs. She was told she had blood clots in her right leg. She stated she had no symptoms of blood clots in her legs like redness, sore, swelling, or hot. She was asked if she had fallen suddenly, had an accident, or was sitting for a long time, traveled a long distances. On 02Apr2021 she had a Echocardiogram and was told her heart was ok. Caller stated she was given Lovenox shots in the hospital. She did not have Lot # or Expiry date on the Lovenox. She stated on 02Apr2021 after having two Lovenox shots that day, she met with a Vascular Surgeon who started her on Eliquis that evening. She stated she started taking Eliquis that evening. She stated she took 2 tablets, twice a day, for a week. Now she takes one tablet, twice a day, ongoing. The Eliquis tablet says 5mg. She stated she was discharged on 03Apr2021, that evening. Patient went back to the emergency room on 10Apr2021 after speaking with a nurse at (university name withheld) because she had tightness in the chest but the shortness of breath, her breathing was not as bad. She just didn't felt right. She stated she was not admitted. Patient stated she saw a NP (name withheld) with (university name withheld) Pulmonary the day of 31Mar2021. When discussing the tests performed that day, Chest X-ray, D-Dimer, and Pro INT, CH asked caller the results from them. She did not provide results, just stated she had looked up her results in ""EPIC mychart"" while getting the result information from the office. Where she was instructed to go to the hospital. She went to the Clinic of the Vascular Surgeon at (Hospital withheld) on Wednesday 14Apr2021 and was feeling better. Her second appointment with them will be in July. Where they will do another ultrasound of her legs and talk about the medication. She has an appointment with her primary on 19Apr2021. The outcome of events Trouble</p>
COVID19 VACCINE	PFIZER\BIONTECH	1288373-1	40-49 years	0 days	<p>vaginal bleeding/blood clots at mid-cycle; vaginal bleeding/blood clots at mid-cycle; vaginal bleeding/blood clots at mid-cycle; This is a spontaneous report from a contactable consumer. A 40-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) lot number: EN6206, via an unspecified route of administration, administered in left arm on 15Mar2021 10:30 as single dose for Covid-19 immunisation. Medical history included folate deficiency and allergies to sulfa. There were no concomitant medications. After the first dose on 15Mar2021, the patient had vaginal bleeding/blood clots at mid-cycle. No treatment information was provided. The outcome of the events was not recovered.; Sender's Comments: Based on temporal association reported events causal relationship with BNT162B2 cannot be excluded. Case to be re-assessed upon receipt of new information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1288429-1	50-59 years	0 days	<p>I went back to the hospital and couple days later they told me that actually I have Deep vein thrombosis now in my legs; my Crohn's had caused really bad flare up/I have been in the hospital for 5 days now with the clot and Crohn's Flare; I also have superficial clot in that left leg that was the pain began on the edges/blood clot; the arm is much better now. You know that's not really sore; I just was too tired/extreme fatigue; really bad like pain; Shortness of breath; This is a spontaneous report received from a contactable consumer (patient). A 54-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 2 via an unspecified route of administration, administered in Arm Right on 29Mar2021 (Batch/Lot Number: EN6201) as SINGLE DOSE for covid-19 immunisation. Medical history included multiple sclerosis from an unknown date and unknown if ongoing, ileostomy from an unknown date and unknown if ongoing, back surgery from an unknown date and unknown if ongoing, Crohn's disease from an unknown date and unknown if ongoing, blood clot in arm back from 2014 to an unknown date. Historical vaccine included BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 1 on 08Mar2021 and experienced terrible diarrhea and neuralgia. Concomitant medication(s) included gabapentin (GABAPENTIN) taken for an unspecified indication, start and stop date were not reported; valaciclovir hydrochloride (VALTREX) taken for an unspecified indication, start and stop date were not reported; diazepam (DIAZEPAM) taken for an unspecified indication, start and stop date were not reported; (ZOFRAN) taken for an unspecified indication, start and stop date were not reported; oxycodone (OXYCODONE) taken for an unspecified indication, start and stop date were not reported; lansoprazole (PREVACID) taken for an unspecified indication, start and stop date were not reported. After second dose on 29th (29Mar2021) immediately he was really bad like pain and had shortness of breath. The patient stated that she had a back surgery and so she always felt bad, so she didn't think anything of it. But then she ended up into ER after the second dose and discovered that her Crohn's had caused really bad flare up. She mentioned her foot was looking strange but she was just too tired and left the ER. She then went back to the hospital and couple days later they told her that she actually had deep vein thrombosis now in her legs. She also had superficial clot in that left leg where the pain began on the edges. The patient reported that the vaccine was basically started the Crohn's flare up. The patient also stated that ""the arm was much better now and not really sore"". The patient was hospitalized for DVT from unknown date and for Crohn's flare up for 5 days. The patient underwent lab tests and procedures which included endoscopy, sigmoidoscopy, ultrasound scan: all on unknown date with unknown result. The patient was treated with Entyvio and on blood thinners now for a blood clot. The outcome of pain in extremity was recovering while others was unknown.""</p>
COVID19 VACCINE	PFIZER\BIONTECH	1290128-1	30-39 years	0 days	<p>Patient collapsed at home with cardiopulmonary arrest. He had been complaining of shortness of breath 1 week prior to the event, starting when he received his covid vaccination. The differential diagnosis was pulmonary embolism, myocardial infarction or arrhythmia. CPR was started immediately and patient received tPA during ACLS without return of spontaneous circulation.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1291204-1	40-49 years	0 days	took 2 generic Whole Foods 365 brand Acetaminophen Expiration Date: Jun2020 in Apr2021; ear crystals; Nausea; she wanted to make sure her not feeling well was normal; She had a really bad headache. Clarifying the headache started 1-2 hours after she got the first COVID-19 Vaccine shot; her (left) arm was really sore after she had the COVID-19 Vaccine, but she had expected that; She was still achy in her muscles, but not everywhere. She said her muscles ached from her shoulders up only.; she had a scratchy (sore) throat; she felt tired; she had a little bit of congestion; after she received the COVID-19 Vaccine that she had some clotting, and menstrual irregularities; she had a swollen lymph node in her left arm pit for the last couple days; after she received the COVID-19 Vaccine that she had some clotting, and menstrual irregularities; she had a pressure inside of her head/Her head doesn't feel well. She said she does not quite have a headache, but her head does not feel normal.; This is a spontaneous report from a contactable consumer (patient). A 48-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: EW0170), dose 1 single dose via an unspecified route of administration in the left arm on 16Apr2021 between 3:53 PM-3:55 PM (at the age of 48 years-old) for COVID-19 vaccination. Medical history included hypermobility syndrome from an unknown date and unknown if ongoing, tends to get headaches with her hypermobility issues, and those headaches felt like pain in her head. Reported she was on the hypermobility spectrum with tension headaches, vertigo positional from an unknown date and unknown if ongoing, 3-4 weeks prior to getting the COVID-19 Vaccine, she tried to take a half of a beta blocker pill to treat the benign paroxysmal positional vertigo (BPPV). She said the BPPV had cleared, and she felt better, vestibular migraine from an unknown date and unknown if ongoing had some residual dizziness from the vestibular migraines, Ehlers-Danlos syndrome from an unknown date and unknown if ongoing. She said she did not have a technical diagnosis for Ehlers-Danlos Syndrome (hypermobility) yet, and finally sees a geneticist next month. She said she was on the weaker end of the Ehlers-Danlos hypermobility spectrum disorder, and did not have a definitive diagnosis. She didn't drink alcohol, exercised every day and slept enough. The patient did not receive any previous immunization with the Pfizer vaccine. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Concomitant medications included cyanocobalamin (VITAMIN B-12) taken for an unspecified indication, start and stop date were not reported and ergocalciferol (VIT D) taken for an unspecified indication, start and stop date were not reported. Cyanocobalamin and ergocalciferol were discontinued a week before she got the COVID-19 vaccine to avoid any issues.The patient experienced she had a little bit of congestion on Apr2021, she wanted to make sure her not feeling well was normal on 16Apr2021, she had a really bad headache, clarifying the headache started 1-2 hours after she got the first covid-19 vaccine shot on 16Apr2021, her (left) arm was really sore after she had the covid-19 vaccine, but she had expected that on 16Apr2021, she had a swollen lymph node in her left arm pit for the last couple days on Apr2021, after she received the covid-19 vaccine that she had some clotting, and menstrual irregularities on Apr2021, she had a pressure inside of her head/her head doesn't feel well, she said she does not quite have a headache, but her head does not feel normal on Apr2021, she was still achy in her muscles, but not everywhere. she said her
COVID19 VACCINE	PFIZER\BIONTECH	1292206-1	60-64 years	0 days	Extreme blood clots in lungs and legs
COVID19 VACCINE	PFIZER\BIONTECH	1294661-1	30-39 years	0 days	Blood clots on my legs; tired; This is a spontaneous report from a contactable consumer (the patient). A 30-year-old patient of an unspecified gender received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot number ER8737), via an unspecified route of administration, on 07Apr2021 at 12:30 (at the age of 30 years old) as a single dose in he left arm for COVID-19 immunization. Medical history included COVID-19 from an unknown date and unknown if ongoing. The patient has no known allergies. The patient's concomitant medications were not reported. The patient had received no other vaccines within fourteen days prior to vaccination. The patient experienced ""blood clots on my legs"" on 07Apr2021 at 17:00 with outcome of unknown, and ""feeling drained and tired for two weeks now"" beginning on 07Apr2021 at 17:00 with outcome of unknown. The patient has not been tested for COVID-19 since the vaccination . ""
COVID19 VACCINE	UNKNOWN MANUFACTURER	1180289-1	40-49 years	0 days	SOB, CP, hot flashes that started later in the day she had received the vaccine. Pt admitted on 4/6 with symptoms still present and discharged the following, day with noted improvement in SOB.
COVID19 VACCINE	JANSSEN	1108465-1	50-59 years	1 day	Heart was in A-fib, blood clot formed and had a Left Posterior Parietal Stroke

COVID19 VACCINE	JANSSEN	1120494-1	65+ years	1 day	Pulmonary embolism with acute Cor Pulmonale/hypoxia I had shortness of breath, dizziness, coughing. I had Covid test on 3/12/21 that was negative. Went to Urgent Care on 3/12/21. Gave me an albuterol inhaler which was not effective in relieving symptoms. I wasn't improving, so went to emergency room at the hospital on 03/18/2021. I was admitted to hospital and placed on oxygen and kept overnight. I was also given Xarelto. I am at home and on Xarelto.
COVID19 VACCINE	JANSSEN	1131295-1	65+ years	1 day	pulmonary embolism
COVID19 VACCINE	JANSSEN	1139939-1	60-64 years	1 day	PT CALLED ON 3-27 TO REPORT A BLOOD CLOT IN HER EYE AFTER RECEIVING THE VACCINE ON 3-13, STILL PRESENT
COVID19 VACCINE	JANSSEN	1168274-1	65+ years	1 day	About 24 hours after the vaccine administration, he became unresponsive at the nursing home. He was sent to the hospital where he is now on a heparin drip due to bilateral Pulmonary Embolisms and multiple DVTs.
COVID19 VACCINE	JANSSEN	1182945-1	40-49 years	1 day	Massive nose bleed with a huge blood clot to follow. Went to urgent care but it had stopped by then so they sent me home and told me if it happened again to go to ER. I haven't had a nosebleed in years so it was scary to get it the day after my vaccine. The nose bleed lasted about 10 minutes and was very strong once the clot came through it slowed down and then stopped and did not return again.
COVID19 VACCINE	JANSSEN	1192294-1	30-39 years	1 day	Fever 100 degrees for 36 hrs Fatigue for 48 hrs Headache for 1 week post Menstrual cycle started 6 days early Menstrual cycle was heavier and many clots noted
COVID19 VACCINE	JANSSEN	1200702-1	30-39 years	1 day	Had a huge blood clot come out of my nose after a nose bleed. I do not get nose bleeds so this was very strange. Took me 15 minutes to get it to stop bleeding.
COVID19 VACCINE	JANSSEN	1201389-1	18-29 years	1 day	Believe I may have passed a blood clot through urine or vagina early this morning. It appeared to be quarter sized. Non painful, one time event. Also have intense back pain and leg aching. Still feverish and have mild headache as well.
COVID19 VACCINE	JANSSEN	1202713-1	40-49 years	1 day	Slight fever 12 hours later. Headache the next day. Severe headache with nausea two weeks later that lasted more than a day. Notice a small dot in left forearm. No pain, though.
COVID19 VACCINE	JANSSEN	1203268-1	50-59 years	1 day	3 blood clots along the left arm where the vaccine was administered.
COVID19 VACCINE	JANSSEN	1203273-1	60-64 years	1 day	Patient reports that several hours after receiving the vaccine that he became short of breath, he was taken to the hospital via ems, Diagnosed with blood clots at hospital. Reports he is now on blood thinners. I spoke with the patient and told him I would be reporting this information and that he may be contacted.
COVID19 VACCINE	JANSSEN	1203443-1	30-39 years	1 day	The adverse symptoms I experienced were abnormally severe/heavy menstrual bleeding and abdominal pain. I was on Day 4 of my menstrual cycle on the day of my injection (April 3, 2021). My menstrual cycle usually starts to go away on Day 4 and concludes by Day 7. But the day after my injection, in addition to experiencing the common side effects of fever, chills, aches, and headaches, I also experienced an uptick in bleeding, which included severe/heavy menstrual bleeding with very frequent and large blood clots. That same day (April 4), I started my new birth control cycle as prescribed. By Day 8 (April 7, 2021), my menstrual bleeding continued to be so severe/heavy that I went to my OB-GYN for testing. The OB-GYN ruled out everything but the vaccine as an environmental factor. It was suggested that I take 600mg of Motrin every 6 hours for 48 hours. My menstrual bleeding continued for several more days until concluding on Day 12 (April 11, 2021) but I am still experiencing abdominal pain.
COVID19 VACCINE	JANSSEN	1204344-1	40-49 years	1 day	patient developed leg pains bilaterally. went to emergency room and diagnosed with DVT in right leg
COVID19 VACCINE	JANSSEN	1204744-1	40-49 years	1 day	Woke with: Blood Clots in my left arm at injection pt and lower arm, wrist, hand. Blood Clots in my left leg, mainly calf, lower leg, ankle, some in thigh. Larger, more numerically present than in past from antihistamines. None present before Vax, allergen-free diet prevents usually.
COVID19 VACCINE	JANSSEN	1204833-1	30-39 years	1 day	Blood clot at injection site in left arm. Place where I was injected still hurts and feels like there is a bullet lodged under my skin when I touch my arm. The pain isn't as severe as it was last week but the blood clot is still there under my skin.
COVID19 VACCINE	JANSSEN	1208872-1	40-49 years	1 day	On March 20th I received the J&J covid-19 vaccine shot. Starting on March 21st I begin to experience symptom such as fever, chills and body aches. That lasted for about 2 weeks. The week of April 5th- I been to experience struggling the ability to breathe. I was having serious pain in my left side of my chest and in the lower left side in my back. It was so severe, I went to the hospital on April 8th and at the hospital the Doctors discovered I had blood clots in my lung. I was in the hospital for 2 days. Iam currently on blood thinners inhaler and and oxygen.

COVID19 VACCINE	JANSSEN	1209032-1	60-64 years	1 day	Persistent rectal bleeding and passing blood and blood clots for 7 days since vaccination. Bleeding occurs with stool and throughout the day, requiring the use of pads.
COVID19 VACCINE	JANSSEN	1209183-1	65+ years	1 day	Patient was vaccinated at 2PM (4/12/21) and caregiver said that at 4AM during the night(4/13/21) patient woke up very nauseated. She immediately vomiting and it contained blood. As she vomited more, numerous clots came out which resulted in caregiver calling 911. Patient was admitted immediately to hospital where she remains today (4/14/21). Doctors have performed an endoscopy and other tests to determine the source of the blood clots and treatment options. Caregiver is available if more details are needed.
COVID19 VACCINE	JANSSEN	1210072-1	65+ years	1 day	Pt received the Johnson&Johnson vaccine on 3/23/2021 in the morning and completed her hemodialysis treatment without any problems. Pt stated she always feels her access before she goes to bed at night and in the morning when she wakes up. Per pt, when she woke up around 0600AM on 3/24/2021 she could not feel the thrill in her access and went to the dialysis clinic for further assessment. Pt's nephrologist was informed as well as her vascular surgeon and was able to fly to location on 3/24/2021 to have her access de-clotted. Pt returned to location on 3/24/2021 and was able to complete her hemodialysis treatment that evening without any complications. Per pt, when she woke up on 3/25/2021 she again could not feel the thrill in her Lt upper arm AVG. Pt came to the dialysis clinic for her hemodialysis treatment on 3/26/2021 and staff confirmed that no bruit or thrill could be auscultated or palpated. Pt flew to location that night and has surgery to have her access de-clotted again on 3/27/2021. Pt flew back to location on 3/27/2021 and was able to complete her hemodialysis treatment without any problems. No further clotting problems with pt's access since.
COVID19 VACCINE	JANSSEN	1211121-1	60-64 years	1 day	Whether the adverse events were caused by the vaccine is to be determined. We are available to discuss more details if this information can be used to help others from experiencing these reactions. The morning after getting the vaccine, patient discovered that she could not swallow. As her condition worsened, she was taken to the emergency room. Over the past month, patient went to the emergency room 4 times. The last time resulted in extended hospitalization that continues to this day. In addition to the swallowing problem, two other major adverse events need to be highlighted. First, on 27 March, while in the hospital, vaginal bleeding started. On 29 March, her doctor, performed a hysteroscopy/DNC finding "" ""an unexplained blood clot (hematoma)."" The second major event was when patient demonstrated significant confusion and lack of memory. On 7 April, she was diagnosed with Metabolic Encephalopathy. Neurologists at the hospital suspected that her MS was reacting to her UTI and once the infection is eliminated her memory should come back. But as of 10 April, she was still having issues including hallucinations. Although she is eating some as of 13 April, she is still very weak and will likely be moved from the Hospital to a rehab facility. She still does not remember much of the last 37 days.""
COVID19 VACCINE	JANSSEN	1211215-1	30-39 years	1 day	Confirmed DVT right lower extremity
COVID19 VACCINE	JANSSEN	1212529-1	40-49 years	1 day	I went on Sunday March, 14, 2021 to get the Johnson and Johnson shot offered through the school system. I noticed that my blurred vision intensified. I went to the eye doctor 3/16 and that is where they found blood clots behind my right eye close to my center. I was referred to a Retinol specialist 3/26/21 and sent me to get a physical to check for diabetes. It had started to heal a little. There was not clear diagnosis on what could have been causing the the blood behind my eye. 4/2/2021 Went for physical at PCP and results of physical was good with no Diabetes.
COVID19 VACCINE	JANSSEN	1212673-1	40-49 years	1 day	Blood Clot and bruising on lower backside of leg, I noticed leg Pain (just uncomfortable) in the right leg at the location of clot. A time frame in relationship to the time of shot is unknown. Estimated within 24 hours. Bruising appeared morning of 04/14/21, PCP recommended in person visit. I went to urgent care, they had me drive to emergency Room at local hospital. Evaluation, blood testing and imaging concluded a blood clot in the lower right leg. Blood thinners was prescribed Eliquis 5 mg, discharged same day. It may be possible the hospital had submitted this form on my behalf.
COVID19 VACCINE	JANSSEN	1212931-1	65+ years	1 day	Stroke caused by blood clot - Vision Impairment and memory impairment

COVID19 VACCINE	JANSSSEN	1212936-1	40-49 years	1 day	Got COVID (Janssen) vaccine shot on April 6th at noon. Felt fine Tuesday and went to bed as normal. Woke up April 7th at 7AM with sharp pains in my left shoulder (same side as shot) and slight shortness of breath, and slight chest pain in the left quadrant of my torso (same side as shot). Proceeded to take Advil and seemed to help a bit. Minor aches/pains and shortness of breath throughout the day until about 8PM. At this time shoulder chest pain became more severe, and breathing became very strained, short, and painful. Pain and breathing kept getting worse and at midnight on Wednesday night thought I was having a heart attack due to extreme chest pain, couldn't breath, lightheaded, dizzy, tingly extremities. My wife drove me to ER at 12:30 AM Thursday.
COVID19 VACCINE	JANSSSEN	1213411-1	60-64 years	1 day	The day after having been vaccinated with Johnson & Johnson/Janssen COVID19 vaccine (04/11/2021), my mother started to feel intense pain, swelling, tenderness and cramping in her legs, especially her right leg, to the point that she couldn't walk. By the fourth day after the vaccine her right leg was completely swollen, twice as big as its normal size, the pain was unbearable and she experienced fatigue and shortness of breath. I took her to the ER on 04/14/2021
COVID19 VACCINE	JANSSSEN	1214389-1	60-64 years	1 day	Patient was diagnosed with a DVT. Also had symptoms of nausea and vomiting which preceded the vaccine.
COVID19 VACCINE	JANSSSEN	1215510-1	50-59 years	1 day	Woke up Sunday the day after and couldn't walk. Waited to see if it would wear off the next day was admitted into emergency with a minor stroke caused by a blood clot
COVID19 VACCINE	JANSSSEN	1216146-1	30-39 years	1 day	Janssen COVID-19 Vaccine EUA Patient received Janssen vaccine 4/9/2021. Patient presented to ED 4/14/2021. Patient is a very pleasant 32-year-old female, with past medical history significant for taking bromocriptine for prolactin issues as well as metformin for type 2 diabetes, presents to the emergency department for evaluation of continued headache over the last 1 week. Patient also reports chills, sweats, body aches ever since receiving the Johnson and Johnson coronavirus vaccination 1 week ago. The headache started after receiving the vaccination and has been continuing ever since. It does not fluctuate in intensity. It is caused her blurred vision and difficulty focusing. No tinnitus or hearing loss. No slurred speech, vomiting, numbness or weakness or tingling to the extremities or any facial droop. No history of strokes or aneurysms. She is not on blood thinning medication at all. No upper nor lower extremity swelling or redness. No abdominal pain, nausea, vomiting or diarrhea. She reports the continued subtle shortness of breath and body aches since the vaccination as well. No rapid heart rate, long flights, long car rides, surgeries nor oral contraceptive use. Patient started on heparin drip. Neurologist recommended transferring patient to higher level of care. emergency department physician is willing to accept the patient at their facility. Patient transferred to the facility.
COVID19 VACCINE	JANSSSEN	1216189-1	65+ years	1 day	78 year old woman admitted with severe back pain, inability to ambulate and leukocytosis on 3/31/21. History of hypertension, CHF, obesity, chronic kidney disease, and back pain. Work up included multiple consults. The patient was placed on SQ heparin for VTE prophylaxis. Acute L5 fracture was found along with emphysematous changes. Neurosurgical evaluation- no surgery was necessary. During the first 24 hours (before receiving the vaccine), the patient's Hg dropped 9.3 to 6.8 and platelets dropped 130K to 61 K with no apparent bleeding source. PRBC transfusion was given. GI consult was obtained the patient was scheduled to have EGD the following morning (day 3). Cardiology was obtained for elevated troponin and hypoxia. An echo obtained on day 2 showed moderate elevated pulmonary artery pressure, mild to moderate tricuspid regurgitation, and normal sized right atrium and ventricle. The patient received the Janssen vaccine upon request the morning of hospital day 2 (4.1.21 at 11:02). At 11:37PM on 4/1/21 the patient received 5mg IV metoprolol for elevated HR of 132 (BP 129/67). At 0128 on 4/2/21 the patient's heart rate dropped into the 60's and then declined further requiring cardiac resuscitation. The attempt was unsuccessful and the patient expired at 01:43 on 4/2/21. An autopsy was conducted (results available on 4/13/21) showed a 4 cm clot in the patient's right atrium and a mural thrombus in her femoral artery.

COVID19 VACCINE	JANSSEN	1216619-1	18-29 years	1 day	<p>On 03/18/2021 at 03:30AM I had a lot of arm pain from my shoulder to my elbow in my left arm. This lasted until 03/31/2021. On 03/18/2021 I woke up with a headache that would not go away. Next, at about 03:15PM I was not able to walk for about 10 minutes. Then, at about 05:00PM I started menstruating. At 07:00PM I had severe pain in my pelvic area for an hour and a half. At approximately 08:30PM I passed a softball sized blood clot vaginally. I bled heavily through the night. On 03/19/2021 I still had a headache and no energy at all. I continued to bleed heavily all day as well. 03/20/2021 was the exact same as the days prior. 03/21/2021 I was still bleeding heavily throughout the day with no energy. I still had the headache as well. I started feeling dizzy while walking on this day. 03/22/2021 I went to work like normal. I was cold all day. I was still bleeding, headache and dizziness. It was hard to stand for 30 minutes. While climbing the stairs I got very light headed and dizzy. I could not go up the stairs at a normal pace. 03/23/2021 I had the same symptoms all day but I was getting short of breath walking short distances. I still had very little energy and a headache. I also lost all color in my face and hands. I was still cold all day. I noticed some slight swelling in my ankles. 03/24/2021 The symptoms were getting more intense. I was still cold. I finally took some aspirin for the headache because it was very severe. The medication didn't help with it. This routine went on for the next week and the symptoms intensified with each day. Throughout this time I was still passing clots that ranged in size from golf/ping pong ball to baseballs. They were very painful when they passed. The days from 03/25/2021 to 04/01/2021 were all the same as far as how I felt. On 04/02/2021 I woke up with the same symptoms but now I could not stay awake for anything. I slept on and off all day. I only ate one meal a day because I was so tired and I had no appetite. The headache was getting worse as the days went on. The bleeding was still happening. It was not as heavy as the weeks before, but enough to be painful still. I also started having abdominal pain. On 04/03/2021 I was seeing stars when I moved too quickly. My heart rate was elevated with shortness of breath along with the rest of the previous symptoms. My headache however was very intense. 04/04/2021 I still couldn't stay awake on top of all the other symptoms. The dizziness and stars were more frequent. I couldn't move my head without seeing stars. 04/05/2021 I couldn't get warm and I still felt the same way. I called and made a doctor's appointment for Wednesday the 7th. I had all the same symptoms still and they were getting worse. I had to move in slow motion so I could try to function. 04/06/2021 I woke up drained of all my energy and color. I couldn't shower because of the pain in my body. I couldn't stand because I felt like I was going to fall down. I could barely stand up straight let alone walk very far. I was shaking from being so cold. I had all the same symptoms from the days prior. I was in severe pain. I couldn't sit because of the pain in my abdomen I couldn't stand because of the weakness in my legs. I could barely see anything because of the stars I was seeing. At this point I had no color and I was barely conscious. That is when my family took me to the emergency room.</p>
COVID19 VACCINE	JANSSEN	1218255-1	30-39 years	1 day	<p>Received Janssen COVID vaccine on 3/19/2021 around 8 am. Was in ER on 3/20/21 around 3 pm. Was found to have acute occlusive deep venous thrombosis of the left popliteal vein, peroneal veins and one of the paired left posterior tibialis veins proximally.</p>
COVID19 VACCINE	JANSSEN	1218283-1	50-59 years	1 day	<p>Headache, shortness of breath which were progressively worsening, evaluated in ER at hospital and found to have two sub-segmental PE's. He was started on oral anticoagulation with xarelto and discharged home in stable condition.</p>
COVID19 VACCINE	JANSSEN	1220652-1	30-39 years	1 day	<p>Blood clots (i started heavy menstrual cramps a day after the shot and I saw exceeding amount of blood clots which has never happened this excessively before) Fever, chills, headchae, nausea (all very severe level)</p>
COVID19 VACCINE	JANSSEN	1223502-1	40-49 years	1 day	<p>received Janssen J &amp; J shot 9:15 am on April 7th approx, 24 hours later had to leave work for home because I became incredibly weak, tired and without energy. struggled at driving home had to repeatedly slap my face to stay awake. checked my temp. when arrived home, had a low fever (100.1) went to bed slept for 4 hours, checked temp (100.1) went back to sleep. woke 9 am on 4/9/2021 checked temp. (normal) fever broke on 4/9/2021 used restroom at 11:01 am 4/9/2021 large amount of bleeding from rectum LARGE AMOUNTS of blood clots in stool (shaped like Candy) Contacted medical provider. Spoke to a triage nurse, explained my concerns about bleeding from rectum and blood clots in stool... she dismissed that my restroom issues were related to the vaccine,</p>

COVID19 VACCINE	JANSSEN	1223789-1	60-64 years	1 day	My sister, received the J & J vaccine on March 5th. I now know that she was not feeling well for a few days afterwards. She then felt better until day nine after the vaccine. On the evening of the ninth day, she began having abdominal pain, vomiting & diarrhea, headache. This was Sunday evening. Unfortunately I wasn't aware of how she was feeling and she didn't go to the emergency rm. until Tuesday morning. Tests determined her platelet level was low and abdominal CT showed bleeding from her adrenal glands. She was given platelets, pain meds and admitted into the hospital. Later that night staff felt she wasn't responsive and a head CT was performed. It was determined she had a brain hemorrhage and emergency surgery was performed. It is my understanding that there was brain damage at that point. During the early morning hours of the 10th day, post surgery, a repeat CT scan was done showing more hemorrhaging and blood clots. She also developed a DVT and PE and was kept on a respirator until the 13th day post vaccine to allow family to say their goodbyes. On the morning of the 13th day patient was removed from life support and she passed.
COVID19 VACCINE	JANSSEN	1223855-1	18-29 years	1 day	Chills 12 h after receipt of vaccine followed by low grade fever (101 F) and body ache with minor headache. Symptoms subsided by the end of the following day. 1st menstrual period post-vaccination was noticeably heavier with more clots than usual.
COVID19 VACCINE	JANSSEN	1226722-1	60-64 years	1 day	Vomiting and Diarrhea day after vaccine. 6 days after shot blood clot and stroke, currently in ICU.
COVID19 VACCINE	JANSSEN	1229680-1	40-49 years	1 day	Received Janssen vaccine 4/6. Started menstrual cycle 12 hours after vaccine even though had just completed last cycle 1 week prior. Normally cycles are 28-30 days apart. They have not been quite as regular since Covid and has had some shorter periods between normal cycles. After the vaccine bleeding was heavier than normal with large clots but by end of last week had changed color and looked like it was ending. Today had no discharge upon awakening but again has a small amount of bright blood. Of course, there is concern for coagulopathy related to the vaccination. No leg pain, no shortness of breath. Has had HA off and on since had Covid but no worse now than in previous weeks. Left ear pain has been painful since Covid but now has pain in both ears when that occurs. Quit taking ibuprofen last week for discomfort and switched to Tylenol.
COVID19 VACCINE	JANSSEN	1230416-1	65+ years	1 day	Presented with right hand/arm pain, numbness, and weakness since morning after receiving injection on ipsilateral side. Workup and imaging confirmed acute arterial thrombosis of the right upper extremity requiring surgery and thrombectomy.
COVID19 VACCINE	JANSSEN	1236791-1	30-39 years	1 day	Client awoke with chest pain and visited local ER for suspect M.I. Transferred to Hospital for angioplasty, related to thrombosis in R) coronary artery. Treated for 3 days and released to home with 3 months of follow-up cardiac rehab. Scheduled to return back to work as an auto mechanic on 4/26/2021.
COVID19 VACCINE	JANSSEN	1241684-1	18-29 years	1 day	admitted to hospital that evening with acute intracerebral hemorrhage felt to be from a cerebral venous thrombosis with dense left hemiplegia. one week later, developed bilateral upper extremity cephalic vein thrombosis that the following week, 4/21/21, continued to propagate
COVID19 VACCINE	JANSSEN	1246956-1	65+ years	1 day	Stroke and blood clot in right leg.
COVID19 VACCINE	JANSSEN	1247505-1	65+ years	1 day	DVT within 24 hours of vaccine
COVID19 VACCINE	JANSSEN	1251532-1	18-29 years	1 day	Patient stated she needed to go to hospital for adverse reaction of pain in leg. After asking MD to check her leg, they discovered a blood clot per patient. She is now doing well per her.
COVID19 VACCINE	JANSSEN	1258387-1	60-64 years	1 day	3 Blood clots formed in the bottom of my left leg.
COVID19 VACCINE	JANSSEN	1259409-1	50-59 years	1 day	4/17 Vaccination @ 530PM 4/18 woke up with stiff neck. Unsure if chest pain started on 4/18 or 4/19. Stiff neck felt like 'being choked'. 2 sharp pains in between breasts. Little pains on left breast, worked up to neck and ear. 4/19 ER. 4/20 ER ultra sound 4/21 cardiologist cb to tell me I had a pulmonary embolism. The Dr. said I needed to go to larger clinic. 4/22 Larger Clinic. They ran some scans with contrast of neck because of pain. CT. Taking blood clot medication. 4/26/2021 Extremely dizzy; going to have a CT scan today **dizziness is so bad right now. *4/29 appt with pulmonologist
COVID19 VACCINE	JANSSEN	1259807-1	60-64 years	1 day	I woke up from almost like a pop in my brain and fluid started pouring down my throat and I started choking. I woke up and was able to spit some of it out. It was clear and also tinged with blood. It stopped once I stood up. I immediately thought my brain was leaking. I told my daughter about this the next day. My balance was off and I had a weird flapping in my head for the next few days. As well as a headache. A few days after I heard about the blood clots. I am not 100% sure if it was from the shot but it was literally hours from when I received it. It was very scary.

COVID19 VACCINE	JANSSSEN	1262527-1	40-49 years	1 day	on the 2nd i had the shot in the left upper arm .. two days later i woke up to violently upchucking pure water after that i when to hospital and was admitted i was told after a ekg that i was haveing a heart attack after that have no recolection of anything i wake up to a doc telling ,e it was a bad heart attack and had delovped about 5 blod clots in left lung and microcadtitis i have been trying since then for a doc to talk to me but so far i been avoided
COVID19 VACCINE	JANSSSEN	1263506-1	40-49 years	1 day	Patient started to have left leg pain. Presented to facility on 4/26/21. Ultrasound examination showed DVT
COVID19 VACCINE	JANSSSEN	1267512-1	65+ years	1 day	Patient developed shortness of breath the day after the vaccine and was diagnosed with bilateral pulmonary embolism and DVT and had to be hospitalized.
COVID19 VACCINE	JANSSSEN	1270282-1	50-59 years	1 day	She got the vaccine, when they put the needle in she said it was far in. The pain was bad, but she could deal with it. Then 5 days later something hit her and hit her bad. She went to the ER and they gave her Bentyl, diarrhea medicine as she was vomiting, not eating anything, and they gave her some anti-vomiting medicine. They sent her home and said she would feel better. The diarrhea and vomiting stopped but she then started with a rash. it's all over her hands, arms, back, itching, and taking Claritin for it. it won't go away. Her symptoms continued to worsen, and woke up one morning and had so much pain that she could not move or breath and her husband called an ambulance and they took her hospital and diagnosed with a blood clot. She was in the hospital for 3 days and now discharged on Eliquis. She has bruises all over her coming out and very upset that she is still feeling bad and doesn't know how the rash is going to go away. She was also prescribed Oxycodone for pain and also Tessalon Perls to take for coughing.
COVID19 VACCINE	JANSSSEN	1280115-1	65+ years	1 day	See below
COVID19 VACCINE	JANSSSEN	1285510-1	60-64 years	1 day	60 yo male with BMI 30 and vodka x 2-3 bottles per day. In hospital 4/9-14 for obstructive uropathy of undetermined origin. In hospital on 4/12 and got J & J there. 4/13 with no prior history developed a DVT. D/C'd on 4/14 on Eliquis. Found unresponsive 4/19. At autopsy, found pulmonary thromboemboli
COVID19 VACCINE	JANSSSEN	1290307-1	50-59 years	1 day	I woke up at approximately 9:30 AM the morning of Sunday May 2nd 2021 the day after getting my covid vaccine and had to rush to the bathroom. I proceeded to have blood and blood clots come out my urethra very urgently. I had abdominal pain and pressure. I proceeded to need to urinate blood and blood clots for approximately 4 hours urgently. I could not go far from the bathroom without having to return quickly to the toilet. I wet myself several times. The clots stopped coming around 1:30 PM. I proceeded to have to have no control over urination urge and could not leave the bathroom. Around approximately 2:00 PM I could leave the bathroom without fear of wetting myself. I continued to have a small amount of a mix of blood and normal urine passing for another hour or so. I have a picture of the blood and clots that came out of my urethra. I continue to have dull pain and pressure in my abdomen.
COVID19 VACCINE	JANSSSEN	1292143-1	50-59 years	1 day	lips and nail beds blue, 4/3/21 bumped left leg,,big bruise, felt clots, headache, metallic taste in mouth,
COVID19 VACCINE	JANSSSEN	1293356-1	50-59 years	1 day	4/10/2021 vaccination 4/11 or 4/12 at the latest, I started feeling a pain in my R calf. It was constant pain for a week and decided to go to the walk in clinic. Blood work which was high and they referred me to the ER and administered a sonogram. *positive for blood clot Eloquence for 30 day starter pack. PCM is going to extend till July in which he will administer another sonogram. *COVID +; 01/2021
COVID19 VACCINE	MODERNA	0927096-1	60-64 years	1 day	Day 2 (12/29/20): Fever (<100 degrees), Mild muscle aches, Fatigue Day 3 (12/30/20): Fatigue, Muscle aches Day 4 (12/31/20): Alternating chills and profuse sweating starting at 8am, Full body flushing, Grand Mal Seizure at 4:30pm
COVID19 VACCINE	MODERNA	0951789-1	65+ years	1 day	Blood and small blood clots in urine.
COVID19 VACCINE	MODERNA	0974753-1	65+ years	1 day	Experienced shortness of breath upon minimal exertion 24 hours after having received the vaccine. Called MD 72 hours vaccine received - MD advised hospital ER. Admitted with pulmonary embolism and deep vein thrombosis. Remains short of breath and is on 4L of oxygen. Receiving anti-coagulants.
COVID19 VACCINE	MODERNA	0978002-1	65+ years	1 day	The morning of Jan 20, 2021, Patient was disoriented, could not communicate well, and fell when he tried to get out of bed. He was taken to The Hospital by ambulance about 11:30 am. He is still hospitalized. Emerging symptoms include: passing a blood clot from his mouth, slight pneumonia, high white count, low kidney values, high fever, all of which fluctuated. A blood transfusion was given because of blood in the urine. He has been confused and disoriented until this morning.

COVID19 VACCINE	MODERNA	0989360-1	30-39 years	1 day	Gross hematuria with clots. AKI with elevated creatinine to 2.18 (Baseline <1.0). UA with moderate blood, positive nitrite, moderate LE, >50 rbc's Urine Iytes WNL, Pr:Cr 3.3, Al:Cr 1,245 C3/C4 WNL US with mildly echogenic kidneys, a nonspecific indicator of medical renal disease. ·No hydronephrosis. Thick-walled nondistended urinary bladder. Hgb decreased to 12.9 from 15 Pt underwent a kidney biopsy, pathology is still pending. He received aggressive IVFs and was monitored for 2 days. He was discharged following the kidney biopsy. At that time he was still having hematuria although it was improving and his hemoglobin was stable.
COVID19 VACCINE	MODERNA	0994135-1	30-39 years	1 day	I am 38 years old with no history of medical problems. I do NOT have a history of miscarriages and have one healthy child who is 22 months old. On 1/13/21, I took a home pregnancy test which came back positive. At that time, I had a missed period but also had several common pregnancy symptoms such as bloating, acne, fatigue and tender breast. later that week, I called OB/Gyn and spoke to an RN to schedule my 8/9 week ultrasound and to inquiry about the vaccine during pregnancy since I had no clue whether it was recommended/safe or not. the RN, very confident and without any disclaimer, stated that hospital is recommending all of their pregnant patients to receive the vaccine. Obviously, I decided to trust this medical professional who was so confident in her response. My normal pregnancy symptoms continued. On 1/19/21, I was 5 weeks pregnant and received my first dosage of the vaccine. felt fine other than a sore left arm. on 1/20/21, I woke up with a lot of abdominal cramping and pain. It was new to me but assumed it was normal. My cramping and pain continued until 1/21/21. On 1/21/21, I woke up without the cramping and pain. But, I also noticed that my breast were no longer tender and my skin had completely cleared up. I became concerned but prayed everything was fine since my home pregnancy test was still positive. On 1/22/21, by cramps continued once again but more mild. My pregnancy symptoms seemed as if they were no longer present but remained hopeful. On 1/23/21, I woke up with light spotting that only lasted through the morning. Soon after, I started having extreme abdominal pains. I prayed everything was fine. The pain continued and became worse. That night, the pain was so bad that I just went to bed. Right before going to bed, I noticed I had started spotting again. A little heavier than in the morning. I made sure to lay on my left side, hoping it was normal in pregnancy. On 1/24/21, I woke up with heavy bleeding and dotting. I went to the doctor and got an ultrasound and blood test. I was told by the doctor at Hospital that I had a miscarriage.
COVID19 VACCINE	MODERNA	0998832-1	18-29 years	1 day	Shortness of breath and severe Chest pain. Ended up being a pulmonary embolism. Placed on Eliquis.
COVID19 VACCINE	MODERNA	1008492-1	18-29 years	1 day	Pt received first dose 1/5/2021. Pt received second dose 02/01/2021. Pt started to have SOB and tachycardia 2/2/20201. She presented to Hospital and was diagnosed and admitted with a pulmonary embolism. She is a paramedic in our EMS system. It is not known to me whether she had other risk factors for a pulmonary embolism.
COVID19 VACCINE	MODERNA	1012962-1	40-49 years	1 day	On Wednesday 1/27 the day after my second dose I felt a minor pinch/discomfort on my lower leg. I did not think much of that is reason I did not report it right away. Day by day the discomfort and pain got worse. Exactly one week after my second dose I was not able to sleep due to the pain. On Wednesday 2/3 I decided to go urgent care. From there I was referred for an ultra sound a few hours after. After the ultra sound I was contacted by my doctor, letting me know that the results showed I had a blood clot on my left leg. I was put on Eliquis medicine right away. On 2/5 I was able to physically see my doctor who told me that this was caused by the second dose of the moderne vaccine that I took on 1/26.
COVID19 VACCINE	MODERNA	1015814-1	50-59 years	1 day	Resident developed low grade fever next day and it continued through Monday morning with some mottling starting to appear on resident's skin. Sent to ER on Monday. Resident sent to higher level of care and diagnosed with pneumonia and bilateral pulmonary embolism
COVID19 VACCINE	MODERNA	1016123-1	30-39 years	1 day	Day after (2/8/21): Severe chills, tiredness, body aches, headache, loss of appetite, fever (101.4), bloody nose w/blood clots (left nostril only). 2 days after (2/9/21): Intermittent headache, aches in joints, bloody nose w/blood clots (left nostril only), hive around injection site.
COVID19 VACCINE	MODERNA	1016814-1	18-29 years	1 day	Pulmonary Embolism 27 year old female presented to ED with chest pain and shortness of breath that began within 24 hours of receiving second Covid vaccine injection on 1/29/21. Chest pain subsided with Tylenol and time, but shortness of breath persisted, worsening on 2/8/21 which brought patient to ED. CTA confirmed PE diagnosis and treated with out patient oral therapy - Xarelto.
COVID19 VACCINE	MODERNA	1033966-1	65+ years	1 day	post vaccine fever, hypoxia, pulmonary embolisms

COVID19 VACCINE	MODERNA	1038250-1	65+ years	1 day	<p>Sadle embolism in lungs; DVT in left leg; Slight fever; Extreme fatigue; Shortness of breath, struggling for every breath; Low o2 sat; A spontaneous report was received from a health care professional, who was a 73-year-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced shortness of breath, slight fever, extreme fatigue, left leg deep vein thrombosis (DVT), and saddle pulmonary embolism (PE). The patients' medical history was not provided. No concomitant medications list was provided. On 24 Dec 2020, prior to the onset of symptoms, patient received the first of two planned doses of mRNA-1273 (Batch number 011J20A) for the prophylaxis of COVID -19 infection. On 25 Dec 2020, patient experienced shortness of breath with low oxygen saturation levels. On 26 Dec 2020, the patient's oxygen saturation levels were down to 89% with slight fever and extreme fatigue. On 27 Dec 2020, patient's energy was back to normal. On 28 Dec 2020, the patient woke up in the morning with symptoms of almost could not breathe, could not walk across the room. The patient's vital signs included oxygen saturation 83%. The patient was struggling for every breath. The patient tested negative for COVID-19. On 30 Dec 2020, another COVID-19 test was negative. On 31 Dec 2020, patient's vital signs included oxygen saturation closer to 90%, and she reported getting better. Symptoms remained the same for about a week. On 08 Jan 2021, the patient experienced left ankle and foot swollen. The patient was seen by physician and then sent to emergency room where it was determined that the patient had DVT in the left leg. A computerized tomogram (CT) scan found clots in the left lung, or saddle PE. On 09 Jan 2021, the patient was discharged from the hospital. Treatment for the events experienced included intravenous heparin and blood thinners. Action taken with planned second dose of mRNA-1273 in response to the events was not provided. The event, extreme fatigue, was considered resolved on 27 Dec 2020. The outcome of the events, shortness of breath, slight fever, DVT and saddle PE were not provided. Follow-up received on 19 Jan 2021 included updated events (DVT and saddle PE), updated event details, treatment, and hospitalization details.; Reporter's Comments: This spontaneous report refers to a case of 73- year-old female patient who experienced serious event of pulmonary embolism and deep vein thrombosis and non-serious events of shortness of breath, oxygen saturation levels were down to 89% with slight fever and extreme fatigue the next day after administration of the first dose of mRNA-1273, lot # 011J20A, expiration date-unknown. Based on temporal information provided and the known safety profile of the vaccine and the absence of any other etiology factors, a causal association between the vents of shortness of breath, oxygen saturation levels were down to 89% with slight fever and extreme fatigue and the administration of mRNA-1273 vaccine cannot be excluded. Fever and fatigue are consistent with the known safety profile of mRNA-1273 vaccine. There is no enough information t clinically assess the causal association between the events of pulmonary embolism and deep vein thrombosis as the patient's medical history and list of concomitant medications were lacking. Main field defaults to Epossibly related'</p>
COVID19 VACCINE	MODERNA	1045548-1	65+ years	1 day	<p>blood clot in the lungs; UTI; COVID-19; Fatigue; Loss of appetite; A spontaneous report was received from a consumer concerning an 87 years-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced blood clot in the lungs/MedDRA PT: pulmonary embolism, loss of appetite/MedDRA PT: appetite lost, UTI/MedDRA PT: urinary tract infection, COVID-19/MedDRA PT: COVID-19, and fatigue/MedDRA PT: fatigue. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. The patient received their first dose of two planned doses of mRNA-1273 (Lot# 041L20A) in left arm (route of administration not provided) on 16 Jan 2021 for prophylaxis of COVID-19 infection. On 17 Jan 2021, the patient experienced fatigue and loss of appetite. On 24 Jan 2021, patient experienced UTI and tested positive for COVID-19. On 31 Jan 2021, the patient was hospitalized and was found to have a blood clot in the lungs. Treatment details were unknown. Action taken with mRNA-1273 was unknown. The outcome of events blood clot in the lungs, loss of appetite, UTI and COVID-19 were unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>
COVID19 VACCINE	MODERNA	1048841-1	65+ years	1 day	DVT Right leg Femur

COVID19 VACCINE	MODERNA	1051872-1	65+ years	1 day	Moderna COVID-19 Vaccine: The morning after injection, she developed shortness of breath, fever, muscle pains, joint pains, delirium. 911 called. EMTs transported her to Hospital where she was admitted after blood tests and CT angiogram of the chest indicated multiple pulmonary emboli in right upper and lower lobes of the lung. Unconscious at the time of admission. Discharged after 3 days. Continues to have significant shortness of breath. Unknown if this will be permanent or lead to death. Reasonably stable at present time although unable to function.
COVID19 VACCINE	MODERNA	1052707-1	30-39 years	1 day	Chief Complaint fever and chills, body aches x3 days. also complains of intermittent chest pain since yesterday 02/20/21 10:28 History of Present Illness This is 31 year old male with no significant past medical history. Patient is health care provider and working in surgical center. Patient has COVID 19 second dose of vaccination on Wednesday and he was feeling sick after that including fever, chills and tiredness. He had chest pain started Thursday and which is in left side of the chest and mostly constant in nature and intensity was up and down and highest intensity was 7/10. No aggravating and relieving factor, denied any shortness of breath, leg swelling. He visited to urgent care and had 12 lead EKG and which showed ST changes in inferior lead and transfer to hospital ER. He is currently having pain about 1/10 intensity. He denied any nausea, vomiting, urinary and bowel symptoms. (sic) Assessment/Plan Chest pain with elevated troponin NSTEMI vs myocarditis post COVID 19 vaccination
COVID19 VACCINE	MODERNA	1053127-1	65+ years	1 day	patient developed unprovoked deep venous thrombosis in left leg one day after receiving 2nd Moderna vaccine
COVID19 VACCINE	MODERNA	1057786-1	50-59 years	1 day	Within 12 hours of receiving my second vaccine, My left leg felt like it internally rotated and started to hurt and feel like lead. On January 28, 2021, I went to the ER and an extensive blood clot (DVT) was found.
COVID19 VACCINE	MODERNA	1061270-1	60-64 years	1 day	Individual received her COVID vaccine and had no prior symptoms. 24 hours after the injection she developed significant shortness of breath and was seen in the ER where she was diagnosed with bilateral pulmonary embolism.
COVID19 VACCINE	MODERNA	1064361-1	65+ years	1 day	Four blood clots in left leg
COVID19 VACCINE	MODERNA	1072189-1	65+ years	1 day	Started dry cough for three day, pain across the lower back began two days after cough. Began intense pain with nausea and cold and clammy sweats. Called the nurse on my insurance who advised to get to the ER.
COVID19 VACCINE	MODERNA	1073412-1	65+ years	1 day	Initial flu-like symptoms with fever Tues -Friday. Had a right side stroke 6 AM Saturday morning. Rushed to hospital and had a procedure involving a catheter through the body to the clot in the brain. Came out of that with a weekend left side and was medicated through Sunday night. At 10:30 PM Sunday night had a second stroke on the right side. Did not wake from that. Now I'm not expected to survive.
COVID19 VACCINE	MODERNA	1073752-1	65+ years	1 day	On February 24 and 25 and 26 my hands and feet swelled on the 27th my left hand turned purple and very inflamed
COVID19 VACCINE	MODERNA	1074082-1	40-49 years	1 day	My stomach was hurting while urinating and there was blood in my urine. At another instance, there was a small blood clot.
COVID19 VACCINE	MODERNA	1075295-1	65+ years	1 day	Vaccine received 2-27, developed sore arm that night, woke next morning with chills and developed temperature 102.2-103 when checked, poor appetite and weak, slept most of day. Felt better until woke in the night on 3-3-21 with chest pain, unable to get comfortable, no relief with ibuprofen, some relief with aspirin. Pain persisted next day on 3-4-21 so seen in Emergency room and diagnosed with pericarditis and 2 pulmonary emboli.
COVID19 VACCINE	MODERNA	1075363-1	65+ years	1 day	Death due to Moderna 2nd dose, pulmonary thromboembolism
COVID19 VACCINE	MODERNA	1088120-1	65+ years	1 day	Called nurse line 4 days after 2nd Moderna vaccine, SOB, fainting, can't eat, dry cough, nose bleeds since shot. Advised to go to ED, patient refused as she feels a bit better today. Called again the following day with same symptoms - again advised to go to ED and quarantine for flu/covid-like symptoms. Patient agreed to come to ED, found to have bilateral PEs and RLE DVTs. Covid/flu negative. LUE red/swollen at injection site - no cellulitis. Admitted overnight and d/c'd home the following day.
COVID19 VACCINE	MODERNA	1088297-1	60-64 years	1 day	Next day developed right leg pain. Following day diagnosed with a new deep venous thrombosis of the popliteal vein, right leg

COVID19 VACCINE	MODERNA	1088646-1	65+ years	1 day	following evening back pain lower left side for 2 days. Moved to stomach on left side and back. At this time urine was orange in color and had a foul odor for 3 days followed by stomach pain still but more intense and dysentery. Called Dr office when I had blood clots the size of quarters or better, Nurse suggested I go to emergency. I did not, this continued for 3 days and then subsided. I still am having chills and a temp of 96.7.. At this point I am concerned to get the second vaccine on the 29 th of this month.
COVID19 VACCINE	MODERNA	1088932-1	65+ years	1 day	Patient received dose #2 of moderna vaccine on 3/2/2021. The next morning (3/3/21) she had a syncopal event with LOC for several minutes. She recovered and was not evaluated by physician until 3/9/21. On 3/10/21, she had a CTA of chest showing bilateral PEs.
COVID19 VACCINE	MODERNA	1092490-1	65+ years	1 day	Patient became lethargic, extremely tired, unable to care well for self. Patient had no appetite, refused most food and spent many hours simply sitting in her chair. She felt that she was having a heart attack and called 911 using her emergency response button on 2/21/2021. Doctors indicated that the patient's life was in serious danger, but because of age they were hesitant to try to remove the clot pressing on her heart. She was only allowed to go back home because we utilized Hospice. When asked about her life expectancy, we were told she could die any minute or might live a few more months, but that she was not expected to live much longer. SHE WAS IN GOOD HEALTH PRIOR TO THE IMMUNIZATION!
COVID19 VACCINE	MODERNA	1094443-1	30-39 years	1 day	Sweating, low-grade fever, chills, body aches, exhaustion, headache. I took Tylenol for 24 hours starting when I woke up at 6am to help with symptoms. It took about 36 hours for my symptoms to be gone after they started. I was also on my period when I received the vaccine. My period seemed to slow down almost completely while my symptoms were happening, and then my period resumed with abnormal cramping and clotting after my symptoms were gone.
COVID19 VACCINE	MODERNA	1095212-1	65+ years	1 day	Saddle Pulmonary embolus occurred on March 6th the day following his first COVID-19 vaccine. He was found to have an extensive right leg DVT but no symptoms. He has no prior history of DVT/PE, no family history of DVT/PE, No known risk factors for DVT/PE.
COVID19 VACCINE	MODERNA	1095584-1	65+ years	1 day	IVC thrombus w/wedge-shaped R-sided pulmonary infarct, suspect PE. Pt initially on Lovenox 100mg subQ bid., started on Apixaban 10mg PO bid for 5 days followed by Apixaban 5mg PO bid for 5 days. Pt continued to demonstrate need for supplemental O2 w/O2Sat 86% on room air at rest, d/c from hospital with home O2.
COVID19 VACCINE	MODERNA	1101283-1	65+ years	1 day	Pulmonary embolism with onset 1-2 days following 2nd dose of Moderna vaccination. No other precipitating events found
COVID19 VACCINE	MODERNA	1108656-1	65+ years	1 day	The next day, I had short term memory loss. I went to the hospital, and they said I had some type of heart episode. I was taken by ambulance to the hospital and was told I had a blood clot in my brain and had suffered a mini stroke. I was hospitalized for 4 nights. I was given blood thinner and I improved.
COVID19 VACCINE	MODERNA	1109886-1	Unknown	1 day	Lungs filled with blood; A regulatory report from was received from a consumer concerning a 57-year-old, male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and reported his lungs were filled with Blood. The patient's medical history was not included. No concomitant medication was included. On 05-Mar-2021, prior to the onset of the events, the patient received his first of two planned doses of mRNA-1273 (Lot number: 026A21A) intramuscularly on his left arm for prophylaxis of COVID-19 infection. On 06-Mar-2021, approximately one day after receiving mRNA-1273, patient was hospitalized due to his lungs was filled with blood. He was treated there and discharged on 08-Mar-2021. Action taken with mRNA-1273 in response to the events was not reported. Outcome of the event lungs filled with Blood were considered as resolved on 08-Mar-2021.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1115432-1	65+ years	1 day	Jan 27th Began to run fever from the shot Jan 28th Continued to experience fever, uncontrollable chills, upset stomach, diarrhea through the day around 6PM I began to sweat, my stomach became upset again, diarrhea grew worse. Chest pain began and call to 911 was placed. Taken to hospital by flight
COVID19 VACCINE	MODERNA	1116539-1	65+ years	1 day	Patient developed rib pain on Friday night March 12, chest and chest wall pain after the shot, Sat night it was more severe, could not lay down, thought it was muscle pain originally. It continued to get worse. Patient went to hospital on Monday March 15th, was diagnosed with a pulmonary embolism with partial infarction of right lower lobe. Was hospitalized until Wed March 17th.

COVID19 VACCINE	MODERNA	1123188-1	65+ years	1 day	Prior to the vaccine on 2/13/21, He was a healthy 65 year old active college professor. 32 hours after the vaccination on 2/14/21, He had acute pancreatitis, which led to septic shock and respiratory failure, and he was placed on a ventilator at Hospital. On 2/24/21, he was transferred to Hospital and continued to have additional diagnoses, including polyneuropathy critical illness, acute gangrenous cholecystitis, abdominal pain, anemia, impaired mobility, oropharyngeal dysphagia, pulmonary embolism, and assistance with ADL. On 3/19/21, he was transferred from Hospital to Acute Rehab Unit for acute physical, occupational, and speech therapy. He remains there today. We do not know if this sequence of events is related to the vaccine, but because it occurred one day after the vaccine, we thought it should be reported.
COVID19 VACCINE	MODERNA	1127847-1	65+ years	1 day	Participant felt flushed, feverish, fatigued with general aches and dry cough over the weekend after receiving injection, took acetaminophen and cough syrup on Monday. He became short of breath on 1/20/2021 and was hypoxic on oximeter check, was sent to the ER. He was intubated in ER and went into respiratory failure with sepsis due to COVID19. He was treated with tocilizumab, became paralyzed and DVT in left lower extremity was found. HE required pressors and diuresis, he developed AKI and hyperkalemia. On 2/21 he was in multi-organ failure. His level of cognition decreased until he was no longer responsive and he died on 2/24/2021.
COVID19 VACCINE	MODERNA	1128838-1	Unknown	1 day	lost appetite; so tired, thought could not get out of bed; Big/ huge clots, came out in a spit; had 3 nose bleeds; A spontaneous report was received from a 77-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced 3 nose bleeds/ Epistaxis, big/huge clots, clot came out in a spit/ Thrombosis, tiredness/ Fatigue, and loss of appetite/ Decreased appetite. The patient's medical history was not provided. No concomitant product use was reported. On 12 Feb 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: unknown) intramuscularly for prophylaxis of COVID-19 infection. On 13-Feb-2021, the patient experienced 3 nose bleeds with huge blood clots. The bleeding was persistent throughout the day, stopping at the intervals and later on the same day it was reported the patient had a huge clot come out in spit. On 14 Feb 2021, the patient was tired, could not get out of bed, and had lost appetite. On 18-Feb-2021, the patient woke up feeling normal. Treatment information was unknown. Action taken with mRNA-1273 in response to the events was not provided. The outcomes of the events were not provided.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1129669-1	65+ years	1 day	Blood clot in my left leg; A spontaneous report was received from a consumer concerning a 71-year-old, male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced deep vein thrombosis. The patient's medical history was not provided. Concomitant medications was not reported. On 14-FEB-2021 prior to the onset of the events, the patient received the first of two planned doses of mRNA-1273 (Lot number: 030M20A) in the left arm for prophylaxis of COVID-19 infection. The next day after receiving mRNA-1273, the patient developed a blood clot in left leg and extended from upper left leg down into his lower leg. He went to the emergency room and was treated for the event with Xarelto. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the event deep vein thrombosis was not reported.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1130189-1	18-29 years	1 day	Patient received Moderna Covid19 vaccine on the 18th of March. Patient began to experience symptoms the next day (shortness of breath, general body pains) on the 19th. Discovered that patient had bilateral PE on the 23rd. Physicians unable to confirm or deny if vaccine was a contributing factor, but due to timing I am reporting this. Patient received treatment for ~24 hours and
COVID19 VACCINE	MODERNA	1130360-1	65+ years	1 day	Patient developed shortness of breath the day after receiving his first Moderna vaccine. Symptoms increased over the next five days. Patient presented to the ED on 3/12/21 after being found hypoxic at their Primary Care doctor's office with O2 sats in the 60s. Patient was admitted to Hospital for pneumonia. Patient continued to require increasing amounts of high flow nasal canula O2 to maintain O2 sats and was diagnosed with multiple segmental pulmonary emboli on 3/16/21. On 3/17/21, patient was also diagnosed with a DVT on the right lower extremity.

COVID19 VACCINE	MODERNA	1140041-1	65+ years	1 day	Acute Submassive Pulmonary embolism B/L
COVID19 VACCINE	MODERNA	1143980-1	60-64 years	1 day	Blood clot in lung, wheezing, coughing
COVID19 VACCINE	MODERNA	1145526-1	30-39 years	1 day	3/13- First shot of Moderna vaccine received. 3/14- Sore arm, chills and a headache. 3/15- Shortness of breath and rapid heartbeat. 3/16- Went to ER because of more severe shortness of breath and rapid heartbeat. 3/17- COVID test with negative result. 3/19- Patient messaged her PCP explaining persisted symptoms. 3/23- Chest pain and shortness of breath developed and she died at ER in PEA. 3/25- Autopsy showed pulmonary embolism with no evidence of peripheral vascular disease. Double check COVID test with negative result.
COVID19 VACCINE	MODERNA	1147604-1	40-49 years	1 day	L JUGULAR AND UE DVT LEFT UPPER EXTREMITY SWELLING ACUTE THROMBOSIS OF LEFT BRACHIAL VEIN ACUTE THROMBOSIS OF LEFT BASILIC VEIN ACUTE THROMBOSIS OF LEFT INTERNAL JUGULAR VEIN
COVID19 VACCINE	MODERNA	1148390-1	65+ years	1 day	Diarrhea, Pulmonary embolism resulting in death
COVID19 VACCINE	MODERNA	1153914-1	65+ years	1 day	dark blood clot coming out of his penis; Gross Hematuria; dark urine; Redness arm; Sore Arm; Swelling arm; A spontaneous report was received from a healthcare professional who was also a 72-year old, male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events redness arm/ vaccination site erythema, sore arm/ vaccination site pain, swelling arm/ vaccination site swelling, gross hematuria/ hematuria, dark blood clot coming out of his penis/ hemorrhage urinary tract, and dark urine/ chromaturia. The patient's medical history was not provided. No relevant concomitant medications were reported. On 10 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot batch: 013L20A) intramuscularly for prophylaxis of COVID-19 infection. On 11 Jan 2021, the patient experienced the events redness, sore arm and swelling. On 20 Jan 2021, the patient experienced the events gross hematuria, with dark blood clot coming out of his penis. The patient had urine analysis (no results provided), and was still urinating dark urine. No treatment information was provided. Action taken with mRNA-1273 in response to the events was unknown. The outcomes of the events, vaccination site erythema, vaccination site pain, and vaccination site swelling, were considered recovered on an unspecified date. The outcomes of the events, hematuria, hemorrhage urinary tract, and chromaturia, were unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested.
COVID19 VACCINE	MODERNA	1153939-1	Unknown	1 day	clot in lung; pain in her left lower lung from back; Shortness of breath; fever 102F; nausea; very very tired; A spontaneous report was received from a female patient of an unspecified age who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced pyrexia (fever 102F), nausea (nausea), illness (very sick), fatigue (very very tired), dyspnoea (shortness of breath) and back pain (pain in her left lower lung from back). The patient's medical history was not provided. No concomitant product use was reported. On 13 Feb 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: unknown) intramuscularly in left arm for prophylaxis of COVID-19 infection. On 14-Feb-2021, the patient felt very sick, had fever of 102 degrees Fahrenheit, nausea, pain in her left lower lung which had radiated from the back, shortness of breath and was very tired. On 15-Feb-2021, the patient got hospitalized and underwent laboratory examination findings of which were unknown. On an unspecified date, it was known that the patient had clot in the lungs and was receiving a daily shot of an unspecified drug as a remedy. On 13 Mar 2021, the patient received their second of two planned doses of mRNA-1273 (Lot number: unknown) intramuscularly in left arm for prophylaxis of COVID-19 infection. The patient took 2X strength of Tylenol right before receiving the second dose of vaccine as per the Physician's recommendation. Treatment information included Tylenol. Action taken with mRNA-1273 was not applicable. The outcome of the events, pyrexia (fever 102f), nausea (nausea), illness (very sick), fatigue (very very tired), dyspnoea (shortness of breath) and back pain (pain in her left lower lung from back), was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events (pyrexia, nausea, back pain, dyspnoea, and fatigue) a causal relationship cannot be excluded. Very limited information regarding these event (Pulmonary embolism) has been provided at this time. Further information has been requested.

COVID19 VACCINE	MODERNA	1155160-1	65+ years	1 day	<p>Patient received Moderna vaccine dose #1 on 3/3/21 at approximately 0900. In the afternoon of 3/4/21, patient had sudden onset shortness of breath while at home, as well as fatigue and low energy. Patient knew that a potential side effect of vaccine was fatigue, so he assumed this was just a normal side effect to be expected. States that his difficulty breathing and fatigue continued for about a week. After continued urging from wife to seek medical care, patient visited urgent care center on 3/15/21. The urgent care did a D-Dimer lab, and an x-ray of chest. X-ray "showed something abnormal" so they did a CT scan as well, which showed a "huge pulmonary embolism." D-Dimer lab was elevated. Patient was transported to hospital by ambulance and had immediate surgery to remove blood clot from lungs at approximately 2100 on 3/15/21. Per patient, the surgeon said the clot was about the size of his palm. Surgeon reported that there was "100% blockage to left lung from the aortic artery and 90% blockage to right lung from aortic artery." A DVT in popliteal vein was identified, and the surgeon assumes the clot started in the popliteal vein and broke off and traveled to lungs. Patient was admitted and hospitalized until he was discharged home on 3/18/21. During course of hospitalization, genetic testing was done and it was determined that the "genetic marker for clots was negative, so they think the clot is from a one-time event—patient's family does not need to be concerned that they have clotting issues." Patient states that he was started on heparin in the hospital, and was discharged home on Eliquis blood thinner, which is being tapered. Patient states that the doctors think he will be on Eliquis for about 6 months and will not need to be on it for life. Doctors say the DVT in leg will dissolve on its own. During hospitalization, an echogram and cardiac cath was performed, which showed "an old heart attack on the left side, but that collateral vessels have built up already." Right side of heart was weaker from having to work so hard due to blood clots in lung, but prior to discharge from hospital, the right side of heart was already showing improvement. A heart cath was done to check vessels and it was determined no stents were needed, although there was a small clot in left anterior descending artery. Patient was also newly diagnosed during course of hospitalization with Type II Diabetes in a non-obese person, HTN (which patient had never had before), Coronary Artery Disease, Hyperlipidemia, 1st degree AV block. Was discharged home with metformin, losartan, chlorthalidone, atorvastatin, and Aspirin. The chlorthalidone was discontinued, due to "blood pressure dropping too low—they think his high blood pressure was situational" per wife of patient. Medical doctors advised against receiving the 2nd dose of Moderna vaccine. Patient being followed by Internist at hospital. Patient's shortness of breath resolved "immediately after clot was removed" but is continuing to be followed while on new medications and blood thinner dosing. The above information was provided during telephone interview of patient and his wife."</p>
COVID19 VACCINE	MODERNA	1159748-1	40-49 years	1 day	<p>The evening (3/20/21) received the vaccine I noticed fatigue, headache and chills. The next morning I developed shortness of breath. The day after that my left leg began swelling for no reason, was slightly discolored and warm to the touch. As the week went on my shortness of breath became greater and my leg more swollen. On (3/26/21) I sent to the ER by my doctor. Had an ultra sound and discovered an extensive DVT in my left groin down to behind left knee. Had a CT and discovered blood clots in my lungs. I had never had any underlying health conditions or been on medications, don't smoke, no complaints prior. Was transported to hospital spent 2.5 days in ICU before being moved to a regular bed for a total of (4) days hospitalized. The doctor installed two sheaths on each side of groin, injected my lungs with medication to blast/dissolve the clots and installed a filter in the main artery to catch any clots that may break away from leg. I was also put on a Heparin drip while in ICU. The next day the doctor went and the procedure was a success dissolving the clots. He removed the sheaths. I went back to ICU. The next day (3/28/21) a second ultra sound was done to left leg and DVT is still in left leg. Have been prescribed Eliquis blood thinner.</p>
COVID19 VACCINE	MODERNA	1168541-1	30-39 years	1 day	Pulmonary embolism
COVID19 VACCINE	MODERNA	1172441-1	65+ years	1 day	Received Covid vaccine on 4/2 and then starting 4/3 starting experiencing nocturnal chest pain. Found to have bilateral pulmonary embolism on evening of 4/5.
COVID19 VACCINE	MODERNA	1173053-1	50-59 years	1 day	Patient states that he woke up the next day extremely fatigued. About 3pm, he could not move his arm/right hand and had trouble walking. He called his doctor's office who told him to call 911. At the hospital, he was given emergency medication for a blood clot. He states the ER told him his stroke was from the covid vaccine.

COVID19 VACCINE	MODERNA	1176319-1	65+ years	1 day	Started with stomach pain that continued to increase. Went to E.R. After various tests found a blood clot near stomach in vein.
COVID19 VACCINE	MODERNA	1179009-1	65+ years	1 day	Blood clot (brain)/ stroke
COVID19 VACCINE	MODERNA	1179596-1	60-64 years	1 day	Patient presented to ED due to sudden onset of chest pain and dyspnea. Symptoms worsened with exertion and relieved with rest. She received 2nd dose of Moderna Covid-19 vaccine on 4/4/21 and began having left calf pain on 4/5/21. She was mildly hypoxic on room air with ambulation and tachycardic. Prior COVID 19 infection in December 2020. CTA showed bilateral moderate burden of disease and was found to have developed bilateral pulmonary emboli.
COVID19 VACCINE	MODERNA	1186147-1	40-49 years	1 day	03/25 - day after shot, developed calf tightness, weakness, chills, shortness of breath, and headache. Discomfort continued for several days. 04/05 - SOB continues to increase, patient experienced lightheadedness and passed out without losing consciousness. 04/06 - continues to have increasing SOB, fainted and lost consciousness. 04/08 - ultrasound done to leg, found DVT, sent to ER
COVID19 VACCINE	MODERNA	1186196-1	65+ years	1 day	fever and associated shivering day after the injection. Severe incapacitating muscle spasm in left leg two days after injection. Three weeks later second muscle spasm but not as severe. Discomfort in leg persisted and diagnosed through ultrasound blood clot in left leg.
COVID19 VACCINE	MODERNA	1197044-1	60-64 years	1 day	Patient received the 2nd dose of Moderna COVID Vaccine on Wednesday 4/7/2021. He called the office today 4/12/2021 at approximately 9:00AM. He stated that his left arm was swollen from the shoulder, down to the fingers. He said that the swelling started on Thursday 4/8/2021, and has not improved. I scheduled him to come into the office for an appointment with PA, at 10:20AM today, 4/12/2021. Patient was sent him to have an ultrasound, which showed DVT in the left subclavian vein and internal jugular vein.
COVID19 VACCINE	MODERNA	1198032-1	65+ years	1 day	Patient has had L leg blood clot and multiple mental co-morbidity-Anemia, hypertension, heart disease, hypokalemia, liver enzyme off per MD, poor nutrition, tremors, hypothyroidism, COPD, small vessel disease of the brain
COVID19 VACCINE	MODERNA	1198907-1	65+ years	1 day	Left calf pain & swelling on 1/28/21. Seen in ED on 1/28; diagnosis left calf DVT. Started double dosing of Eliquis twice daily. Leg swelling increased and upper left leg began to swell. Seen in ED again on 1/31/21; new ultrasound showed extensive clotting both lower and upper left extremity. Continued double dosing of Eliquis with no resolution of clots. Seen by cardiovascular surgeon on 2/10/21; new ultrasound showed continued extensive clotting, now in pelvis as well as entire left leg. Referred to Interventional Radiologist. Procedure performed on 2/12/21: TPA & heparin infused through popliteal vein for 24 hours/in the intensive care unit
COVID19 VACCINE	MODERNA	1202465-1	50-59 years	1 day	Presented to the ER with chest pain lasting 2 hours
COVID19 VACCINE	MODERNA	1203182-1	65+ years	1 day	Morning on 3/11 awoke with fever and body aches, breathing became difficult over the next several days, along with light headedness. ED visit on 3/14 diagnosed with COPD flare advised to follow up with PCP. 3/22 follow up with PCP, discovered blood in stool sent to ED. Admitted on 3/22 with low hemoglobin and blood in stool. Endoscopy on 3/23 and colonoscopy on 3/24. Source of bleed undetermined. Released on 3/23. 4/1 returned to ED as symptoms continued. D-dimer blood test and CAT found blood clots in lower right lung. Prescribed Eliquis and released. Returned to ED on 4/5 admitted with low hemoglobin (7.1) bleeding, breathing difficulty. Endoscopy repeated on 4/6 not bleeding found. Released on 4/9.
COVID19 VACCINE	MODERNA	1207984-1	65+ years	1 day	I did not feel well starting the day after my second Moderna shot, 2/15/2021, arm swollen, hard and red throughout week. Started having difficulty breathing within a couple of days, brushed it off and tried to function as normal but by 2/21/2021 I could no longer function and had difficulty breathing if I tried to do anything and went to emergency room. Diagnosed with multiple blood clots in both lungs.
COVID19 VACCINE	MODERNA	1208119-1	30-39 years	1 day	I began to have a fever with chills and very severe body aches that lasted 3 days after the shot and developed the day after the shot was administered. In addition, I developed a rash on my arm and was bedridden. I took a small walk that day and proceeded to swell up on the left side of my body but it subsided within a few hours. The next day, I suffered a stroke due to blood clotting and the clot flowing to my brain. I had to go to the hospital and was there for a few days.
COVID19 VACCINE	MODERNA	1208240-1	65+ years	1 day	severe basal artery thrombus and sequelae

COVID19 VACCINE	MODERNA	1212213-1	65+ years	1 day	shortness of breath, feet aching progressed to extremities and weakness - increased shortness of breath even with increasing oxygen. To ER on 03/27/2021 - elevated D-Dimer 41.40 (nl < 0.50) - CT chest - Pulmonary embolism in distal left and right pulmonary arteries extending into all lobar pulmonary arteries and several segmental pulmonary arteries bilaterally - right ventricular enlargement showing right heart strain. Admitted to hospital - discharged initially on 03/31/2021 - back to ER 03/31/2021 and finally discharged on 04/05/2021 on Xarelto
COVID19 VACCINE	MODERNA	1212536-1	65+ years	1 day	I developed a pulmonary embolus after my second Moderna covid-19 shot. My PSO2 dropped to 86% and Doppler found that i had an extensive DVT in my right leg, of which I was unaware. I have had no cardiovascular issues prior to this - I'm average weight, don't smoke and had no know risk factors at the time. I'm undergoing extensive testing now to see if there was a reason for my DVT and PE>
COVID19 VACCINE	MODERNA	1213377-1	65+ years	1 day	pt was vaccinated at 2pm on 4/13/2021 moderma vaccine lot 021b12a and on 4/14/2021 at 830 had sharp lung pain was sent to the hospital and was admitted with a PE
COVID19 VACCINE	MODERNA	1214852-1	65+ years	1 day	2/25–4 days after second COVID vaccine patient visited ED for c/o SOA and dyspnea. Chest CT shows ""small sized pulmonary emboli in the right middle lobe branches"", Venous doppler shows ""venous thrombosis involving the right posterior tibial venous segment"". Hospitalized for 2 days–discharged home.""
COVID19 VACCINE	MODERNA	1215349-1	65+ years	1 day	Stroke resulting from Blood Clot . Hospitalized at Hospital for three days.
COVID19 VACCINE	MODERNA	1220987-1	65+ years	1 day	blood in her urine with clots; urine was dark like the color of syrup and it was a brown thick stream; sharp severe headache; chills; fatigue; This spontaneous case was reported by a non-health professional (subsequently medically confirmed) and describes the occurrence of HAEMORRHAGE URINARY TRACT (blood in her urine with clots) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 030A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 06-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 07-Apr-2021, the patient experienced HEADACHE (sharp severe headache), CHILLS (chills) and FATIGUE (fatigue). On 08-Apr-2021, the patient experienced HAEMORRHAGE URINARY TRACT (blood in her urine with clots) (seriousness criterion medically significant) and CHROMATURIA (urine was dark like the color of syrup and it was a brown thick stream). On 09-Apr-2021, HAEMORRHAGE URINARY TRACT (blood in her urine with clots) and CHROMATURIA (urine was dark like the color of syrup and it was a brown thick stream) had resolved. At the time of the report, HEADACHE (sharp severe headache), CHILLS (chills) and FATIGUE (fatigue) outcome was unknown. Not Provided No relevant concomitant medications were provided. The patient received acetaminophen for symptoms. She is currently seeking help from her health care provider regarding this situation and is undergoing some tests in the meantime such as a renal ultrasound. Action taken with mRNA-1273 in response to the events was not applicable. Based on the current available information and temporal association between the use of the product and the start date of the event (headache, chills, and fatigue), a causal relationship cannot be excluded. Very limited information regarding the events (Haemorrhage urinary tract, chromaturia) has been provided at this time. The subject's medical history and concomitant medications are required for analysis. Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event (headache, chills, and fatigue), a causal relationship cannot be excluded. Very limited information regarding the events (Haemorrhage urinary tract, chromaturia) has been provided at this time. The subject's medical history and concomitant medications are required for analysis. Further information has been requested.

COVID19 VACCINE	MODERNA	1221095-1	50-59 years	1 day	<p>possible stroke; small clot that went through and resolved on its own; Loss use of left leg/couldn't use her leg; tingling in left arm; This spontaneous case was reported by a consumer and describes the occurrence of CEREBROVASCULAR ACCIDENT (possible stroke), THROMBOSIS (small clot that went through and resolved on its own), MONOPLÉGIA (Loss use of left leg/couldn't use her leg) and PARAESTHESIA (tingling in left arm) in a 55-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 046A21A) for COVID-19 vaccination. The patient's past medical history included Familial hypercholesterolemia, Peripheral arterial disease and Stent placement (has stents in her iliac ery). Concomitant products included ATORVASTATIN CALCIUM (ATORVASTATIN [ATORVASTATIN CALCIUM]), ACETYLSALICYLIC ACID (BABY ASPIRIN) and SERTRALINE for an unknown indication. On 26-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Mar-2021, the patient experienced CEREBROVASCULAR ACCIDENT (possible stroke) (seriousness criterion hospitalization), THROMBOSIS (small clot that went through and resolved on its own) (seriousness criterion hospitalization), MONOPLÉGIA (Loss use of left leg/couldn't use her leg) (seriousness criterion hospitalization) and PARAESTHESIA (tingling in left arm) (seriousness criterion hospitalization). The patient was hospitalized from 27-Mar-2021 to 28-Mar-2021 due to CEREBROVASCULAR ACCIDENT, MONOPLÉGIA, PARAESTHESIA and THROMBOSIS. At the time of the report, CEREBROVASCULAR ACCIDENT (possible stroke), THROMBOSIS (small clot that went through and resolved on its own), MONOPLÉGIA (Loss use of left leg/couldn't use her leg) and PARAESTHESIA (tingling in left arm) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In March 2021, Computerised tomogram: Inconclusive. In March 2021, Magnetic resonance imaging: Inconclusive. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No treatment information was provided. Patient reports an MRI and CT scan was done, and she was informed that they suspected she had a small cot that went through and resolved on its own. Company Comment: Based on the temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However patient's hx of familial hypercholesterolemia, peripheral arterial disease and stent placement are confounding factors that may play a possible contributory role.</p>
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COVID19 VACCINE	MODERNA	1235672-1	65+ years	1 day	<p>blood clots in his right leg and left leg; Emergency Room at 4am because he had trouble breathing and walking; found blood on both his lungs; chills especially at night that lasted 2 nights; He states he is still in misery; Patient was supposed to get second dose on 04-Mar-2021, but he is not going to get it; shoulder pain/hip pain; Pain in arms, leg; trouble walking due to his pain; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (blood clots in his right leg and left leg), DYSPNOEA (Emergency Room at 4am because he had trouble breathing and walking), HAEMOPTYSIS (found blood on both his lungs) and CHILLS (chills especially at night that lasted 2 nights) in an 88-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 004M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Asthma since an unknown date. Concomitant products included MONTELUKAST and FLUTICASON FUROATE, VILANTEROL TRIFENATATE (BREO ELLIPTA) for Asthma, METOPROLOL and APIXABAN (ELIQUIS) for an unknown indication. On 04-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 05-Feb-2021, the patient experienced THROMBOSIS (blood clots in his right leg and left leg) (seriousness criteria hospitalization and life threatening), DYSPNOEA (Emergency Room at 4am because he had trouble breathing and walking) (seriousness criterion hospitalization), HAEMOPTYSIS (found blood on both his lungs) (seriousness criteria hospitalization and medically significant), PAIN IN EXTREMITY (Pain in arms, leg), GAIT DISTURBANCE (trouble walking due to his pain) and ARTHRALGIA (shoulder pain/hip pain). On 04-Mar-2021, the patient experienced INTENTIONAL DOSE OMISSION (Patient was supposed to get second dose on 04-Mar-2021, but he is not going to get it). On an unknown date, the patient experienced CHILLS (chills especially at night that lasted 2 nights) (seriousness criterion hospitalization) and FEELING ABNORMAL (He states he is still in misery). The patient was hospitalized on 20-Feb-2021 due to DYSPNOEA, HAEMOPTYSIS and THROMBOSIS, and then for 2 days due to CHILLS. At the time of the report, THROMBOSIS (blood clots in his right leg and left leg), DYSPNOEA (Emergency Room at 4am because he had trouble breathing and walking), HAEMOPTYSIS (found blood on both his lungs), PAIN IN EXTREMITY (Pain in arms, leg), GAIT DISTURBANCE (trouble walking due to his pain), FEELING ABNORMAL (He states he is still in misery) and ARTHRALGIA (shoulder pain/hip pain) had not resolved and CHILLS (chills especially at night that lasted 2 nights) and INTENTIONAL DOSE OMISSION (Patient was supposed to get second dose on 04-Mar-2021, but he is not going to get it) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Chest X-ray: (abnormal) Found blood on both of his lungs. On an unknown date, SARS-CoV-2 test: (Negative) Negative. On an unknown date, Ultrasound scan: (abnormal) Found blood clots in his right leg and left leg. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Patient was taken to the ER (Emergency Room) on 20-Feb-2021 at 4 AM. Several tests including Chest X-Ray, MRI, Blood work, Ultrasound (groin and legs) were performed. Only few tests results were reported. Received treatment including Oxygen, Eliquis and Antibiotics. Patient has been on oxygen full time until 7Apr2021 Company</p>
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COVID19 VACCINE	MODERNA	1245371-1	65+ years	1 day	<p>irritated her heart condition; Clot blood; weakness in legs, couldnt walk with legs; Coma; couldn't breathe; stroke/massive stroke in left side of her brain; Irritated her heart condition, rapid heart beat; Headache; Tiredness; This spontaneous case was reported by a consumer and describes the occurrence of CEREBROVASCULAR ACCIDENT (stroke/massive stroke in left side of her brain), CARDIAC DISORDER (irritated her heart condition), DYSPNOEA (couldn't breathe), THROMBOSIS (Clot blood), COMA (Coma) and MUSCULAR WEAKNESS (weakness in legs, couldnt walk with legs) in a 95-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for Covid-19 Vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Heart disease, unspecified, Hypertension and AFib. Concomitant products included APIXABAN (ELIQUIS) for Anticoagulant therapy, SACUBITRIL VALSARTAN SODIUM HYDRATE (ENTRESTO) for Hypertension, METOPROLOL for an unknown indication. On 10-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Mar-2021, the patient experienced HEADACHE (Headache) and FATIGUE (Tiredness). On 12-Mar-2021, the patient experienced MUSCULAR WEAKNESS (weakness in legs, couldnt walk with legs) (seriousness criterion hospitalization). On 13-Mar-2021, the patient experienced CARDIAC DISORDER (irritated her heart condition) (seriousness criterion hospitalization), THROMBOSIS (Clot blood) (seriousness criterion hospitalization) and HEART RATE INCREASED (Irritated her heart condition, rapid heart beat). On 15-Mar-2021, the patient experienced CEREBROVASCULAR ACCIDENT (stroke/massive stroke in left side of her brain) (seriousness criteria death and medically significant). On 16-Mar-2021, the patient experienced DYSPNOEA (couldn't breathe) (seriousness criterion hospitalization prolonged) and COMA (Coma) (seriousness criterion hospitalization prolonged). The patient was hospitalized on 13-Mar-2021 due to CARDIAC DISORDER, COMA, DYSPNOEA, MUSCULAR WEAKNESS and THROMBOSIS. The patient died on 17-Mar-2021. The reported cause of death was massive stroke in left side of her brain. It is unknown if an autopsy was performed. At the time of death, CARDIAC DISORDER (irritated her heart condition), DYSPNOEA (couldn't breathe), THROMBOSIS (Clot blood), COMA (Coma), MUSCULAR WEAKNESS (weakness in legs, couldnt walk with legs), HEART RATE INCREASED (Irritated her heart condition, rapid heart beat), HEADACHE (Headache) and FATIGUE (Tiredness) outcome was unknown. Action taken with mRNA-1273 in response to the events was not Applicable. This case concerns an 95 year old female patient, with medical history of A Fib, Heart disease, Hypertension who experienced a serious unexpected event of Death 8 days after receiving 1st dose of mRNA- 1273 . Very limited information regarding these events has been provided at this time. However, the patient's advance age, multiple co-morbidities, may remain as risk factors. Further information is requested. This case was linked to MOD-2021-074814 (Patient Link).; Sender's Comments: This case concerns an 95 year old female patient, with medical history of A Fib, Heart disease, Hypertension who experienced a serious unexpected event of Death 8 days after receiving 1st dose of mRNA- 1273 . Very limited information regarding these events has been provided at this time. However, the patient's advance age, multiple co-morbidities, may remain as risk factors. Further information is requested.; Reported Cause(s) of Death: massive stroke in left</p>
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COVID19 VACCINE	MODERNA	1245419-1	60-64 years	1 day	<p>found several blood clots in her lungs; it (difficulty breathing) became worse; difficulty breathing; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (found several blood clots in her lungs) in a 62-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 039AZ1A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history reported.). Concomitant products included APIXABAN (ELIQUIS) for an unknown indication. On 02-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Apr-2021, the patient experienced DYSPNOEA (difficulty breathing). On 05-Apr-2021, the patient experienced CONDITION AGGRAVATED (it (difficulty breathing) became worse). On 07-Apr-2021, the patient experienced PULMONARY EMBOLISM (found several blood clots in her lungs) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 07-Apr-2021 to 11-Apr-2021 due to PULMONARY EMBOLISM. On 15-Apr-2021, DYSPNOEA (difficulty breathing) and CONDITION AGGRAVATED (it (difficulty breathing) became worse) had resolved. At the time of the report, PULMONARY EMBOLISM (found several blood clots in her lungs) outcome was unknown.</p> <p>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Apr-2021, COVID-19: negative (Negative) Test results came back negative on 06Apr2021. On 07-Apr-2021, X-ray: abnormal (abnormal) Blood clots in lungs. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. After x-ray at urgent care on 07-Apr-2021 showed several blood clots in lungs, the patient was taken to the ER (emergency room) and was subsequently admitted to the hospital. Treatment information was not provided. On 12-Apr-2021 the patient went to their PCP (primary care physician) who stated that the clots most likely were not due to the vaccination and that the 2nd dose was safe for her to receive. At the time of this report on 15-Apr-2021, the patient reported feeling fine. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the events 1-3 days after the vaccination, a causal relationship cannot be excluded. Very limited information regarding these events has been provided at this time. Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events 1-3 days after the vaccination, a causal relationship cannot be excluded. Very limited information regarding these events has been provided at this time. Further information has been requested.</p>
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COVID19 VACCINE	MODERNA	1249676-1	40-49 years	1 day	<p>massive blood clot in the right lung; painful knot under the skin on his arm; threw up about 20 times in 6 hours, and kept vomiting all the next day; massive blood clot in the lung ended up in different parts of the lung causing extreme amount or pain\ Left lung is beginning to hurt again and his chest is killing him; next day when he got up and could barely walk; This spontaneous case was reported by a consumer and describes the occurrence of PULMONARY EMBOLISM (massive blood clot in the right lung), PULMONARY PAIN (massive blood clot in the lung ended up in different parts of the lung causing extreme amount or pain\ Left lung is beginning to hurt again and his chest is killing him) and THROMBOSIS (painful knot under the skin on his arm) in a 45-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 027A21A and 007B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Autoimmune disorder NOS in September 2020 and Broken bones. On 18-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 19-Mar-2021, the patient experienced GAIT DISTURBANCE (next day when he got up and could barely walk). On 26-Mar-2021, the patient experienced PULMONARY EMBOLISM (massive blood clot in the right lung) (seriousness criteria hospitalization, medically significant and life threatening). On 04-Apr-2021, the patient experienced PULMONARY PAIN (massive blood clot in the lung ended up in different parts of the lung causing extreme amount or pain\ Left lung is beginning to hurt again and his chest is killing him) (seriousness criterion medically significant). On an unknown date, the patient experienced THROMBOSIS (painful knot under the skin on his arm) (seriousness criterion medically significant) and VOMITING (threw up about 20 times in 6 hours, and kept vomiting all the next day). On 19-Mar-2021, GAIT DISTURBANCE (next day when he got up and could barely walk) outcome was unknown. On 28-Mar-2021, PULMONARY EMBOLISM (massive blood clot in the right lung) had not resolved. On 04-Apr-2021, PULMONARY PAIN (massive blood clot in the lung ended up in different parts of the lung causing extreme amount or pain\ Left lung is beginning to hurt again and his chest is killing him) had not resolved. At the time of the report, THROMBOSIS (painful knot under the skin on his arm) and VOMITING (threw up about 20 times in 6 hours, and kept vomiting all the next day) outcome was unknown. Not Provided Treatment information provided as blood thinners (IV heparin) and antibiotics were used to treat the events. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-081632 (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-081632:2nd dose</p>
COVID19 VACCINE	MODERNA	1261945-1	40-49 years	1 day	<p>This spontaneous case was reported by a physician (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Developed a pulmonary embolism) in a 45-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 06-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 07-Apr-2021, the patient experienced PULMONARY EMBOLISM (Developed a pulmonary embolism) (seriousness criterion medically significant). At the time of the report, PULMONARY EMBOLISM (Developed a pulmonary embolism) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The concomitant medications and treatment details were not provided. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p>

COVID19 VACCINE	MODERNA	1276686-1	65+ years	1 day	<p>Blood Clot; left knee had red marks above it; pain in thigh; swelling from the knee up to the thigh; left knee was in pain tremendously; difficulty walking; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood Clot) in a 68-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 013620A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 14-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Jan-2021, the patient experienced GAIT DISTURBANCE (difficulty walking) and ARTHRALGIA (left knee was in pain tremendously). On 16-Jan-2021, the patient experienced ERYTHEMA (left knee had red marks above it), PAIN IN EXTREMITY (pain in thigh) and JOINT SWELLING (swelling from the knee up to the thigh). On an unknown date, the patient experienced THROMBOSIS (Blood Clot) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Blood Clot), GAIT DISTURBANCE (difficulty walking), ERYTHEMA (left knee had red marks above it), PAIN IN EXTREMITY (pain in thigh), JOINT SWELLING (swelling from the knee up to the thigh) and ARTHRALGIA (left knee was in pain tremendously) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications like high blood pressure medication, cholesterol medication and medication for irregular heartbeat were reported. On 15 Jan2021, the patient said that his left knee was in pain tremendously and had difficulty walking. On 16 JAN 2021, the left knee had Red marks above it. He also had swelling from the knee up to the thigh. He also experienced pain in the thigh and knee. He went to the doctor on 20 JAN 2021 and was sent for an ultrasound. The doctor thought it could be related blood clot. No laboratory details were provided. On 20-Jan-2021, the patient was sent for an ultra sound, results unknown. Treatment included ibuprofen and paracetamol. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>
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COVID19 VACCINE	MODERNA	1289333-1	65+ years	1 day	<p>March 2 - second Moderna March 3 - spontaneous bruising appears March 4 - visit with primary care doctor, blood work shows significant drop in platelets March 9 - first visit with oncologist/haematologist &amp; hospitalized March 9-19 - hospitalized for tests, treatment to increase platelets, &amp; many blood panels. No official diagnosis, treat as ITP. Follow up visits with oncologist/haematologist to keep an eye on platelets as they increase. March 30-Apr 4 - ER visit due to swelling of ankles, feet, and left arm. Tests show superficial blood clot, fluid on lungs, and pneumonia. Oncologist said that ""we have no official diagnosis"", that she's being treated for ITP. April 6-14 - follow up visit to oncologist/haematologist show elevated kidney enzymes, then later liver enzymes, low sodium. April 14 - decision to move to short term rehab for regular PT and OT. Continued swelling (fluid in third spaces.) April 21 - visit to cardiologist to perform cardioversion, successful (during first week of hospital stay, heart rhythm med had to stop). April 23 - facility nurse discovered significantly low Hemoglobin and a blood transfusion was ordered. April 24 - returned to short term rehab facility. April 25 - discovered my mother on O2 and state of health was different, extremely weak and not moving, arm hurting badly. I insisted that her oncologist is contacted. Transported to ER. Discovered her blood work abnormal. After stabilizing her, rushed to the hospital ICU. April 26 - Discussed with her ICU doctor the history of what you have read above. He explained that the covid-19 vaccination has a tendency to affect three proteins specifically that clot and thin blood. I begged him to ""get it out of her system."" Her bleeding was significant and platelets dropped, again. Still has her mental facilities. Responding well to aggressive treatment: albumin transfusion, plateletpheresis, and CRRT. Pleural catheter to remove fluid from the lungs. Mention of Sepsis. April 27 - Lifted her head up today, opened her eyes, making doctors very happy. Her cardiologist and the ICU doctor both said they were ""confused"" and everything happening to my mom was ""a mystery."" Though going in to the evening, her nurse expressed to me that she's worried. The ICU oncologist called me at home in the evening. He asked me if she had been having a fever on a regular basis. He said he thought it could be TTP or a rare disease called HTH, but both results wouldn't be back for one week. He planned to consult with a doctor. He explained to me that the blood was attacking itself and ""confused,"" and that her organs were shutting down. He indicated that the blood work wasn't indicating significant infection. He referenced how the vaccination has made her auto immune system ""go crazy."" April 28 - I get a call very early from the nurse that she has been fighting with my mother's blood pressure all night, trying to keep it elevated. She told me to come to the hospital, because she had taken a turn for the worse. I arrive to find my mother's eyes wide open, breathing shallow, and blood pressure steady, but drops without assistance from medication. She continues to have her mental facilities. She passed away, organs shutting down, and blood pressure dropped.""</p>
COVID19 VACCINE	PFIZER\BIONTECH	0916795-1	40-49 years	1 day	<p>Soreness at injection site 3 hours post injection. 30 hours post injection, pt experiences a huge blood clot from vagina, about the circumference of a dementine. was not old blood, looked like frank blood. over the next 30 hours, pt experiences more clots, much smaller, about the size of a pea. pt has a headache and chills throughout. 48+ hours, experiencing what feels like menstrual cramps. no blood clots 72 hours post injection</p>
COVID19 VACCINE	PFIZER\BIONTECH	0923031-1	30-39 years	1 day	<p>Worsening arm pain after injection that eventually resulted in my being diagnosed with a blood clot in the arm that I received the injection on</p>

COVID19 VACCINE	PFIZER\BIONTECH	0929169-1	Unknown	1 day	Development of microemboli on distal, fourth right phalange on the ventral surface. Just past the DIP. Small blue hue below skin surface with mild tenderness on deep palpation.; This is a spontaneous report from a non-contactable Physician (patient). This adult female patient (not pregnant at the time of vaccination) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899), intramuscular on 23Dec2020 09:30 at single dose on right arm for COVID-19 immunisation. Medical history included migraine with aura. Concomitant medication included propranolol, loratadine (CLARITINE) and multivitamin. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient previously took cefprozil (CEFZIL) and experienced allergies. The patient experienced development of microemboli on distal, fourth right phalange on the ventral surface. Just past the DIP. Small blue hue below skin surface with mild tenderness on deep palpation on 24Dec2020 12:00. The event was considered as non-serious. Treatment for the events was unknown. The outcome of the event was unknown. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. No follow up attempts are possible. No further information is expected.; Sender's Comments: Based on the close temporal relationship, the association between the event microemboli on distal phalange with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	0934745-1	65+ years	1 day	Resident had seizure like activity followed by a vagel response with large bowel movement. Resident then began to show signs of blood clot to left lower extremity. No pedal pulse, area on leg warm to touch. Left lower leg now cold to touch, stiff, purple and white in color. No other signs of modeling, body warm to touch, no fever noted. Respirations and pulse increased with low oxygen levels. Resident not responding to stimuli.
COVID19 VACCINE	PFIZER\BIONTECH	0949555-1	65+ years	1 day	Received Pfizer vaccine, first dose on Wed. 01/13/21 between 12 and 1 P.M. Thurs. 01/14/21 in the afternoon he began to note that he had difficultly walking. Went to bed when he woke up at 5:48 A.M. he reported he had ataxia. Patient reported having to walk in tiny steps to stay upright. He went to the emergency room. Had CT scan of head and found blood clots. MRI performed. Stroke found in right PCA territory, but no loss in strength in left lower extremity. Sensation and vision intact. Strength in all four extremities is 5 out of 5.
COVID19 VACCINE	PFIZER\BIONTECH	0957860-1	40-49 years	1 day	"I received the Pfizer Covid vaccine Wed afternoon around 4pm. Thursday morning around 9:30 I started with severe pain in my left leg. The pain worsened through the day and my leg began swelling. No other symptoms at all. This morning my leg was twice the size of my right leg so I went to the ER. I live in so I'm at ED. I have a massive blood clot running the the length of my leg - from my thigh to my ankle. I'm very lucky I got here so fast! I'm a very healthy 49 year old with no history of DVT or blood clots so they dug further to find out why. A cat scan showed I have a congenital condition called May Thurner Syndrome. I'm so relieved to have an answer and it?s fixable! The vascular doctors are not 100% convinced that?s not all that was going on as I was born with the syndrome and I've gone this long without a clot. So they are doing lots of labs to see if anything else shows up. This is where we are at. I'm being admitted to take care of the clot."''''''

COVID19 VACCINE	PFIZER\BIONTECH	0961282-1	40-49 years	1 day	Felt like a restless leg or blood clot but not as severe.; Felt like a restless leg or blood clot but not as severe.; Left below knee pain and discomfort. Some to the right leg as well.; Left below knee pain and discomfort. Some to the right leg as well.; Checked back of leg for warmth or bruising lasted day 2 and day 3.; Checked back of leg for warmth or bruising lasted day 2 and day 3.; Did feel some discomfort to left arm as a result of the shot in left arm, tender and could feel when holding arm up some discomfort; This is a spontaneous report from a contactable nurse reporting for herself. A 49-years-old female patient started to receive bnt162b2 (BNT162B2; Lot: ECO142) vaccine , intramuscular in the left arm on 29Dec2020 15:45 at single dose for Covid-19 immunisation . Medical history included hypertension, anaemia, blood cholesterol increased , depression, food allergy (whey casium) (taking doxepin for it with relief). Concomitant medication included doxepin (DOXEPIN), metoprolol (METOPROLOL), calcium ascorbate (VITAMIN C [CALCIUM ASCORBATE]), tocopherol (VITAMIN E [TOCOPHEROL]), cyanocobalamin (VITAMIN B-12) , atorvastatin (ATORVASTATIN), sertraline (SERTRALINE). The patient experienced felt like a restless leg or blood clot but not as severe. on 30Dec2020 07:00 with outcome of recovered , left below knee pain and discomfort. some to the right leg as well. on 30Dec2020 07:00 with outcome of recovered , checked back of leg for warmth or bruising lasted day 2 and day 3. on 30Dec2020 07:00 with outcome of recovered , did feel some discomfort to left arm as a result of the shot in left arm, tender and could feel when holding arm up some discomfort on 30Dec2020 07:00 with outcome of recovered. The event blood clot was considered serious (Important Medical Event). Course of the events The patient reported left below knee pain and discomfort. Some to the right leg as well. She checked back of leg for warmth or bruising lasted day 2 and day 3. She felt like a restless leg or blood clot but not as severe. She felt better to stand instead of sitting. Did feel some discomfort to left arm as a result of the shot in left arm, tender and could feel when holding arm up some discomfort. No shortness of breath, no nausea, no dizziness, no increased fatigue (baseline - not enough sleep - working 3 jobs); Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported leg thrombosis cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	0966427-1	18-29 years	1 day	Patient received Pfizer vaccinations on 12/29/20 and 1/19/21. She woke up on 1/20 with hot flashes, fatigue and chills. Later in the day she developed a headache. This morning (1/22) as she was walking to her car to go to work she developed dyspnea and palpitations. She had a portable pulse ox and noted HR was 125 and PO2 97%. She went to ED, COVID neg, d-dimer positive, CT chest negative for PE. Potassium was low. Patient was discharged home.
COVID19 VACCINE	PFIZER\BIONTECH	0978544-1	60-64 years	1 day	First vaccine small bruise at her left knee and extreme pain in her neck, shoulder and left arm and missed work. Second vaccine she has 4 bruises and clots on her inner leg from ankle to thigh. So painful she can't sleep and she is having a hard time walking. Her left shoulder is limited due to extreme pain. She sought care from her physician and he is sending her for scans that the facility is requiring a deposit.
COVID19 VACCINE	PFIZER\BIONTECH	0979775-1	40-49 years	1 day	Employee states that she received Dose #2 the day after the end of her menstrual cycle and that she began bleeding again after receiving her second dose and that it was a heavy and clotted cycle. She was advised to contact her OB/GYN
COVID19 VACCINE	PFIZER\BIONTECH	0982388-1	40-49 years	1 day	The next morning I started to have some pain in my right calf which worsened throughout the day. The following day I went to the ER with a DVT. I was given Xarelto for treatment.
COVID19 VACCINE	PFIZER\BIONTECH	0985480-1	65+ years	1 day	after second dose of vaccine, patient had Internal jugular (IJ) vein thromboembolism, acute, right; Mucositis; Sore throat. Admitted for Chemotherapy-induced neutropenia; Infection of venous access port. Discharged after one day.
COVID19 VACCINE	PFIZER\BIONTECH	0987016-1	30-39 years	1 day	Extensive left lower extremity/iliac DVT requiring surgical intervention. No history of thromboses. No family history of thromboses.
COVID19 VACCINE	PFIZER\BIONTECH	0989988-1	50-59 years	1 day	Diagnosed day after 2nd shot with ophthalmic artery thrombus causing vision loss/change in left eye. I did get shot series on 12/22/2020 #1 and 1/10/2021 and was diagnosed with Covid-19 on 12/13/2020. My internist MD did not feel the vaccine caused the thrombus /Stroke but I wanted to report it as it was associated with the vaccine administration (symptoms of vision loss within 24 hours of the vaccine #2 administration).

COVID19 VACCINE	PFIZER\BIONTECH	1004777-1	50-59 years	1 day	Headache the next morning after receiving vaccine that hasn't gone away, fluid in left lung, blood clots in right lung and leg.
COVID19 VACCINE	PFIZER\BIONTECH	1006474-1	65+ years	1 day	Within 12 hrs of receiving the vaccine the pt began to experience generalized weakness, chills, shortness of breath with symptoms worsening as time went on. Pt remained afebrile. Pt presented to the ED and was diagnosed with a Pulmonary Embolism.
COVID19 VACCINE	PFIZER\BIONTECH	1012854-1	65+ years	1 day	COVID-19 Pfizer Vaccine dose #1 12/21/20 (Lot EJ1685); Tubersol TB test placed on the same day COVID-19 Pfizer Vaccine dose #2 1/11/21 (Lot EL1284) 1/12/2021: Patient presents to ED via EMS for chief complaint -- He stated that he was diagnosed with COVID-19 in November 2020. The patient has not had any recent Covid 19 exposures. He has not congregated with family members and others for Christmas. He comes in for shortness of breath to the ED that is accompanied by fever. Prior to getting his Covid vaccine 19 he was seen good health. The patient finds that he short of breath, dyspneic on exertion, and feels overall weak and fatigued. He has shaking chills according to him. Patient is diagnosed with PE likely due to untreated DVT (Patient reports ""taking girlfriend's coumadin"" from 1/7.""
COVID19 VACCINE	PFIZER\BIONTECH	1026980-1	65+ years	1 day	Patient reported to Emergency room on 01/23/2021 with complaint of nausea. According to ER record patient reported he received a COVID 19 vaccine Pfizer the day before. Work up in the ER (CT ABD PELVIS) reveal a clotted of SMA. CT CHEST REVEALED BILATERAL PULMONARY EMBOLUS. THE PATIENT WAS TRANSFERRED TO THE STATE HOSPITAL. HE WAS SCHEDULED FOR EMERGENT VASCULAR SURGERY WHICH WAS CANCELLED AS THE PATIENT DIED SHORTLY AFTER HIS ARRIVAL.
COVID19 VACCINE	PFIZER\BIONTECH	1028101-1	65+ years	1 day	Pt develops left leg pain The day after vaccination in AM subsequently drove approximately 150 miles On his way back stopped at his brothers place for lunch. He then collapsed coning down the steps, EMS started CPR. took him to ER Resuscitated briefly but went into CardioPulm Arrest again and PEA Resucitaion for aprox 1 hour but was unsuccessful. Noted to have Left leg more swollen than Right by 3 to 4 CM presumed to have died from massive Pulmonary embolism and inferior wall myocardial ischemia
COVID19 VACCINE	PFIZER\BIONTECH	1030521-1	65+ years	1 day	I am 77 yrs old, male , , 150# and 5ft 6inches...Within 24 hours of receiving the shot, my body thru-up clots in my left leg. and I spent 4 days in the hospital ( 3 days in surgical ICU), breaking up the clots to save the leg. This is too much of a coincidence to ignore and I will not receive the 2nd shot.
COVID19 VACCINE	PFIZER\BIONTECH	1033682-1	65+ years	1 day	L hand edema, hematoma which burst and caused bleeding sending pt to the ER for pressure dressing and 2 stitches. L hand and arm progressively got more edematous and bruised looking (severely black/blue/purple) and the hand continued to bleed and swell on 2/6/21. Severe arterial and venous issues and apparent blood clots. On 2/7/21 there were also lumps noted on left inner thigh. Pt. stopped eating or drinking on 2/8/21 and expired on 2/12/21.
COVID19 VACCINE	PFIZER\BIONTECH	1047435-1	40-49 years	1 day	deep vein thrombosis in lower left leg; mild fever; fatigue; body aches all in the day following injection DVT persists and was diagnosed 6 days later; all other symptoms resolved within 24 hours
COVID19 VACCINE	PFIZER\BIONTECH	1047925-1	65+ years	1 day	At location, she felt fine during 15min wait At 3:30-4:30 Zoom call, she looked good, but said she wasn't feeling great & was concerned due to chills & 4days headaches after 1st dose At 8:30pm she called with chills, 3 layers of clothes & bedwarmer on... said her teeth chattered & was trying to drink warm water to heat from the inside (hydration w/o cold water; said no more coffee) At 11:00pm she texted chills were over, she was expecting aches ?but would be asleep during them?... good attitude at the time At 2:19am she called, had fallen & couldn't get up, said she called a friend to come help her ... said she'd tried to get up, but legs were numb... said she was dizzy when she fell, total dry mouth & had reached for water, but it spilled when she knocked into things when she fell. She wondered if she should call Fire Dept (but wasn't making total sense). Her friend came, tried to help, but I think she decided to call 911 for help getting her up & wants EMTs to check her out. **She had fallen during Covid, went to ER & they gave fluids & she was ?good? for a week, but then dizzy & severe lethargy, same friend took her to ER & she was admitted (negative covid test at that point), but very large PE, thus heparin & then Eliquis (Dec 2020).
COVID19 VACCINE	PFIZER\BIONTECH	1054874-1	60-64 years	1 day	Blood clot large in leg DVT and PE both lungs

COVID19 VACCINE	PFIZER\BIONTECH	1059421-1	65+ years	1 day	After the second vaccine dose she reported not feeling well with unspecified symptoms for a few days. On February 18th, 2021 she visited her doctor with numbness in her hand. They thought it may be carpal tunnel and sent her home. The morning of March 18th, 2021 she had a severe stroke and was transferred to Hospital and then to other hospital. She was in the hospital until Tuesday March 23rd when she was transferred back to her home for hospice care. She died on March 26th, 2021.
COVID19 VACCINE	PFIZER\BIONTECH	1063491-1	65+ years	1 day	Chills, Night Sweats, aches, collapsed a week after 2nd dose and then diagnosed with DVT - entire right leg involved.
COVID19 VACCINE	PFIZER\BIONTECH	1065921-1	65+ years	1 day	right middle cerebral stroke due to clot in brain; right middle cerebral stroke due to clot in brain; This is a spontaneous report from a contactable consumer or other non hcp. A 87-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EL9265), via an unspecified route of administration right arm single dose on 30Jan2021 15:00 for covid-19 immunisation. First dose was received on 09Jan2021 03:00 PM, right arm, lot # EK9231. Medical history included diabetes mellitus, hypertension, hyperthyroidism, glaucoma, drug allergy (to Sulfites). The patient's concomitant medications were not reported. The patient experienced right middle cerebral stroke due to clot in brain from 31Jan2021. The patient was hospitalized from 31Jan2021 to 01Feb2021. The events outcome was not recovered.
COVID19 VACCINE	PFIZER\BIONTECH	1073786-1	30-39 years	1 day	The following day, she complained of headache, fatigue, dizziness, and lightheadedness for 3 days. On 2/19/2021 she experienced hives on her abdomen and back that were itchy. No medicine was taken. On the 2/20/2021, she complained of further headache, fatigue, dizziness. She also had shortness of breath. The next day, she presented to the urgent care. She was given an intravenous fluid bolus for dehydration. She was given a ""migraine cocktail."" She was told that her D-dimer was positive. She had a CT scan that showed sinusitis and her chest was clear. The following day, she complained of progressively worsened ascending pain in her left arm. She had red patches of a rash in her left arm as well. One week later, she went back to the urgent care. An ultrasound was performed and a blood clot was found at. She is now taking Eliquis daily.""

COVID19 VACCINE	PFIZER\BIONTECH	1075308-1	60-64 years	1 day	still have sore muscles in my shoulders; still feeling bad with all the above symptoms; 23Jan2021 went to get covid test but due to blood in my nose received antibody test which was neg; bad headache; winded; vomited; diaherra; coughing/cough; large clots gushed from my rt nostril went to er stopped bleeding after 2 hrs; large clots gushed from my rt nostril went to er stopped bleeding after 2 hrs; This is a spontaneous report from a contactable other hcp (patient). A 61-year-old female patient received their first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EL1283, expiry date not reported), via an unspecified route of administration on the left arm on 20Jan2021 18:45 at single dose for COVID-19 immunization. Medical history included diabetes mellitus and high BP from an unknown date and unknown if ongoing. Concomitant medications included levothyroxine, losartan potassium and sodium fluoride (CREST CAVITY PROTECTION). The patient previously took sepra and experienced allergies. The patient reported that on 21Jan2021, they woke up and brushed their teeth then at 6:40am blood with large clots gushed from their right (rt) nostril. The patient went to ER and stopped bleeding after 2 hrs. On 22Jan2021, the patient woke up with bad headache, winded, vomited, diaherra (as reported), coughing. On 23Jan2021, they went to get covid test but due to blood in their nose, they received antibody test which was negative. On 24Jan2021, the patient was still feeling bad with all the above symptoms. Then on 25Jan2021, they went to ENT doctor who cauterized their nose and stated that since antibody was negative to take the maderna vaccine since they have no antibody in their system, the Pfizer vaccine did not work. From 26Jan2021 to 13Feb2021, the patient felt same started feeling better 14Feb2021 but still have sore muscles in their shoulders and cough. The patient underwent lab tests and procedures which included sars-cov-2 antibody test: negative on 23Jan2021. The action taken in response to the event(s) for bnt162b2 was not applicable. Therapeutic measures were taken as a result of epistaxis and clot blood which include the doctor cauterized their nose. The patient recovered with sequel from the events.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the epistaxis and other reported events due to temporal relationship. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including CBC and coagulation panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1082674-1	65+ years	1 day	Patient received Covid19(Pfizer) vaccine on 02/26/2021 at 3.55pm and on 02/27/2021 in the morning he had swelling in his left leg ( patient had knee replacement in same leg 9 months ago). He waited 2 days and still no improvement. He went to Beaumont urgent care on 03/03/2021 and he was referred to emergency room at hospital. He was admitted due to blood clot in left leg and lungs, where he had leg surgery. He was prescribed Eliquis 5 mg twice a day.
COVID19 VACCINE	PFIZER\BIONTECH	1093361-1	40-49 years	1 day	Acute right index finger digital ischemia after initial complete numbness from PIP joint distally absent any previous symptoms ever. Recurrence Jan 20 of same symptoms. Suspect antibody complex clot blocking terminal branches of digital arteries.
COVID19 VACCINE	PFIZER\BIONTECH	1096852-1	65+ years	1 day	About 27-28 hours after injection felt strong pain in left lung area. Got progressively worse, especially at night when lying in horizontal position. The pain became extreme, could hardly breathe (inhalation causing extreme pain) and couldn't really walk on morning of March 6 (about 66 hours after vaccination. Called General Practitioner and he said to go to Emergency Rm. A catscan showed a small blood clot in each lung. Given blood thinner injection. Subsequent Ultrasound of legs showed no clots there. Released 48 hours later, put on Eliquis – 5mg – two each time, twice a day for 6 days, then one each time twice a day. for 3 months.
COVID19 VACCINE	PFIZER\BIONTECH	1102272-1	65+ years	1 day	Patient developed B PE's within a week of the vaccination. She has had a DVT before, but no other known risk factors
COVID19 VACCINE	PFIZER\BIONTECH	1103572-1	60-64 years	1 day	Chills, blood clot R DVT, Dizzy, balance difficulty, itchy upper torso, sleeplessness
COVID19 VACCINE	PFIZER\BIONTECH	1105195-1	65+ years	1 day	Pain in upper right thigh on day after vaccine and next day. Badly swollen calf on third day after vaccine. Hospitalized with ""Right femoral acute thrombosis; no compression; no flow detected.""

COVID19 VACCINE	PFIZER\BIONTECH	1105251-1	40-49 years	1 day	n/v, chills, SOB, pulmonary embolism, pericardial effusion
COVID19 VACCINE	PFIZER\BIONTECH	1105456-1	65+ years	1 day	Lymph gland under left arm size of golf ball, smaller glands swollen underarm, (soft), neck swollen, left foot swollen, weakness, small blood clot in myopic of middle finger, small modules in upper thigh, sore on lower lip right side
COVID19 VACCINE	PFIZER\BIONTECH	1105500-1	60-64 years	1 day	Pfizer-BioNTech Covid vaccine, first shot developed a blood clot in a superficial vein the day after the vaccine, was diagnosed by a doctor as ""superficial thrombophlebitis, pain swelling in leg. Treatment of ibuprofen started. Wondering if I should take my second shot which is scheduled for MArch 26""
COVID19 VACCINE	PFIZER\BIONTECH	1105772-1	65+ years	1 day	My mother died on February 19, 2021. She had her 2nd dose vaccine on 2/11, on 2/12 it was noted that she was not able to walk, on 2/13 she was walking at 30%, on 2/14 she was walking with difficulty, on Monday 2/15 she was throwing up violently and her blood pressure dropped, so she was sent to Clinic. My sister was told she was just constipated and she had A Fib (never reported before to us). My sister was then told on 2/16 early a.m. that she had a blood clot that destroyed her colon. Due to age surgery would likely not be successful. She then died on the Friday. We are reporting in the event that the Pfizer vaccine was somehow a contributing factor to the A fib or to the Clot. She has no history of A fib or clotting prior to this incident. She was 93, and did have dementia, but was able to eat normal foods prior to this. What was unusual was the challenge in walking the day after the shot. Other than that no difference was observed until the day she was admitted to the hospital emergency room. She was a resident at Assisted Living, Memory Care, and that is where she received the vaccine. The mailing address I provided is her mailing address prior to death.
COVID19 VACCINE	PFIZER\BIONTECH	1105932-1	65+ years	1 day	On Saturday patient woke up saying he was in extreme pain with his left arm. At 5 o'clock that night he lost his equilibrium and I had to call 911. They came and after an initial examination took him to Hospital's emergency room. They did c-scans, MRI. and they said that a blood clot was showing in his brain and that he had atrium fibrillation of his heart. His vision has been affected, though the hospital thinks it will improve. The left side of his body is not function right and he needs a walker to walk. He has been in ICU since Sunday. This is late Tuesday.
COVID19 VACCINE	PFIZER\BIONTECH	1118702-1	65+ years	1 day	Had a stroke 36 hours after getting second vaccine. Lost ability to speak and see clearly, had word salad. Was identified quickly by my wife and was taken by ambulance to hospital where they gave me TPA clot buster infusion after identifying a clot in my left back side of brain and luckily I responded well and have all speech function back we believe so far.

COVID19 VACCINE	PFIZER\BIONTECH	1123131-1	65+ years	1 day	hard of hearing; Headache and then I had muscle aches/Achy and headachy; Headache and then I had muscle aches/Achy and headachy; Little bit of discomfort; Kind of stiff; Trouble in seeing; Used to be 5'7"" but now I am 5'4""; she noticed bright red bleeding in her urine when she emptied her bladder; I just had a taint little bit till the day when I got it and then the next day I went to the bathroom to empty my bladder again and I had bright red bleeding again with some blood clots in it; Skin dry; slept a lot; she felt tired and so rotten; mild low-grade fever; body aches and pains; This is a spontaneous report from a contactable consumer (patient herself). An 85-year-old female patient received her second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EM9810) via an unspecified route of administration on 25Feb2021, 11:00 am as a single dose for COVID-19 immunisation. Medical history included hypertension, stroke, heart attack, COVID-19 in Aug2020 (actually had COVID this summer in August, had the mild case), and emergency surgery in Aug2020. Concomitant medications included ajmaline (CARDIA), isosorbide, and levothyroxine sodium (SYNTHROID) taken for cardiac disorder; and losartan. The patient her first dose on 04Feb2021 and experienced headaches, muscle aches and pains, chills, other flu-like symptoms, heart conditions, and sensitivity to eggs. She mentioned that this was normal and nothing unusual. She received her second dose on 25Feb2021 at 11:00 am. She was still kind of stiff but was okay. The next day on 26Feb2021 at 11:00 am, she noticed bright red bleeding in her urine when she emptied her bladder. After a few hours it faded. On the next day on 27Feb2021, she experienced the bright red bleeding in the urine again. The red blood did not hurt and patient was achy and headachy, ""you know muscles."" So, that kind of happened and it just kind of eased off. She slept a lot because she felt tired and so rotten from Friday, Saturday, Sunday after getting the shot. She also had a mild low-grade fever, headaches, and body aches and pains which she considered normal. Patient was hard of hearing and did not have a bright red bleeding, just had a taint little bit till the day when she got it and then the next day, she went to the bathroom to empty her bladder again and had bright red bleeding again with some blood clots in it. Then she did not really have that much the rest of the day and since then it seems to be clear. She did have a little bit of discomfort and her skin was dry. She have never had that experience before so she was just not sure was that connected with that shot? She wanted to know if there were any other patients that have had that. Patient also stated, ""I have a bit trouble in seeing. So, I am going to have my magnifying glass"" when asked about the product details. She will be getting her annual check up on 24Mar2021 so she will also check with her doctor. She mentions that she doesn't take that much flu-shots because she is sensitive to eggs. Her urine seems to be clear as of the time of report. She wants to know if the bright red bleeding in the urine has been reported. Patient stated, ""I used to be 5'7"" but now I am 5'4"". I think I am weighing about 158 now. I am sorry like I said because of my hearing and with a language difference a little bit. I was having a trouble hearing you."" The patient did not have treatment for the events. Outcome of the events was unknown.""
COVID19 VACCINE	PFIZER\BIONTECH	1124008-1	50-59 years	1 day	Pt admitted with acute pleuritic CP and dyspnea that started the day after vaccination. Found to have bilateral PE
COVID19 VACCINE	PFIZER\BIONTECH	1126808-1	65+ years	1 day	Well he got the shot at 9 in the morning and by 4 in the a.m he had a stoke and it took him 5 hrs to get to his phone for help and called my mother
COVID19 VACCINE	PFIZER\BIONTECH	1129100-1	65+ years	1 day	The evening of 23 Dec 2020 I developed sudden shortness of breath with exertion and was unable to walk to my car in a hospital parking lot without stopping twice. SOB progressed over next few weeks and I sought medical attention.
COVID19 VACCINE	PFIZER\BIONTECH	1133603-1	60-64 years	1 day	DVT day after vaccination

COVID19 VACCINE	PFIZER\BIONTECH	1134398-1	65+ years	1 day	<p>She had been in her usual state of health until tonight. Assisted living facility staff called. He mentioned that the facility staff had earlier noticed that she was dragging her right foot and has been needing more assistance with activities. The patient was walking and did not feel well. She was lowered to the ground and had a witnessed cardiac arrest. The ambulance was called and she was reportedly found to have pulseless electrical activity. She was given Epinephrine and Amiodarone with return of pulse. The patient was brought to the Emergency Room and was evaluated by ER physician. EKG showed atrial fibrillation, ventricular rate = 66, RBBB with Brugada pattern. She was emergently brought to the Cath Lab. Cardiac catheterization showed normal coronary arteries but EF 35-40%. Repeat EKG showed atrial fibrillation with rapid ventricular response = 110, RBBB. Therapeutic hypothermia was initiated. The patient was admitted to the ICU on mechanical ventilation with TV 350 RR 14 PEEP 5. She is sedated with Propofol and Fentanyl IV. She is on Levophed IV. ABG showed pH = 7.22, pCO2 = 53, pO2 = 66, O2 sat = 88%. Lactate level = 9.5. WBC 8.8, Hgb 13.4, Hct 46, Platelets 138. Na 138, K 3.2, Cl 102, bicarb 20, BUN 16, Crea 1.19, estimated GFR = 44 mL/minute. Magnesium 2.7. Glucose levels have ranged from 273-312. Pro-Calcitonin = 0.26. Albumin 3.7. SGOT 262, SGPT 294. Troponin elevated at 47. Pro-BNP = 600. Urinalysis showed large blood. Chest x-ray showed vague peripheral pneumonitis. Endotracheal tube is in place. COVID-19 test by PCR is negative (2/5/21). COURSE IN HOSPITAL The patient was admitted to the ICU and was followed by Pulmonary/Critical Care. Patient was maintained on mechanical ventilation, sedated with propofol and fentanyl IV. Vasopressors were administered (Levophed IV). She was managed with therapeutic hypothermia. She was followed by Cardiology. Foley catheter was inserted for close input/output monitoring. Neuro checks, vital signs, daily weights, pulse oximetry, cardiac telemetry and fingersticks were monitored. She was given sodium bicarbonate IV due to metabolic acidosis. She was also given insulin IV drip. Potassium chloride IV was administered due to hypokalemia. The patient was given amiodarone IV. Platelet count was noted to be low but stable. Glucose levels were within acceptable range. Metabolic acidosis resolved. Hypokalemia resolved. Hypomagnesemia resolved. There were elevated LFTs which improved. Elevated CPK also improved. She was taken off hypothermia protocol. Sedation was decreased and she was able to open her eyes with verbal stimulus but unable to follow commands. Ammonia level was normal. Neurology evaluated the patient. EEG showed left periodic epileptiform discharges consistent with severe diffuse encephalopathy. Chest x-ray revealed right upper lung and left mid lung increasing opacity for which meropenem IV was started. Levophed was discontinued. Initially she had peripheral cyanosis, but this resolved upon discontinuation of vasopressors. Brain MRI was done demonstrating diffuse bilateral small and moderate-sized ischemic foci throughout the cerebellum and cerebellar region suggestive of embolism. There also was chronic marked atrophy and moderate small-vessel gliosis. CIRCUMSTANCES SURROUNDING DEMISE Based on neurologic evaluation, her prognosis for meaningful neurologic recovery was thought to be extremely poor. The patient was evaluated and followed by Palliative Care. She does not have family members and had designated her neighbor friends as her power of attorney. They have known the patient</p>
COVID19 VACCINE	PFIZER\BIONTECH	1135578-1	65+ years	1 day	<p>Developed DVT blood clots in legs and clots in lungs.; Developed DVT blood clots in legs and clots in lungs.; This is a spontaneous report from a contactable consumer. This 68-year-old female consumer reported that she received 2nd dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EN6198) on 06Mar2021 12:30 PM at left arm for COVID-19 immunisation. Medical history included known allergies: Clindamycin and high blood pressure. Historical vaccine was 1st dose of BNT162B2 (lot number EN6201) on 14Feb2021 01:15 PM at left arm for COVID-19 immunisation. Concomitant drugs included hydrochlorothiazide, triamterene (TRIAMTERENE AND HYDROCHLOROTHIAZIDE), omeprazole, nortriptyline hydrochloride (NORTRIPTYLIN). The patient developed DVT blood clots in legs and clots in lungs on 07Mar2021 08:00 AM. Event resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event). Patient was hospitalized for 3 days and received treatment. The patient had computerised tomogram (CAT) scan, ultrasound, echocardiogram. Event outcome was not resolved.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1140670-1	65+ years	1 day	heart attack; pass blood clots in his urine; nauseous; really tired; knocked him on his butt/did not get out of bed, did not do anything for 2 weeks; couldn't stay awake/ slept for two weeks; couldn't eat anything; the sight or smell of food made him gag; bruise on his arm about the size of a half dollar where he got the shot; This is a spontaneous report from a contactable consumer. A 69-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; solution for injection, Lot Number: EN6201), via an unspecified route of administration, administered on the right arm at the age of 69 years, on 18Feb2021 16:00 at a single dose for COVID-19 immunisation. Medical history included known for a history of heart disease, stage 4 kidney failure and polycystic disease. He had been bleeding from the kidneys for a week prior to receiving the vaccine, heart attack and cholesterol. He stated he needs some reassurance and added he has Stage 4 kidney failure with polycystic disease. He already consulted with his heart doctor and kidney doctor and they say get the vaccine. He mentioned that every now and then he gets blood from a cyst rupture. On the day of the first shot he was having a little bit of bleeding in his urine. Concomitant medications included acetylsalicylic acid, ascorbic acid (ASPIRIN [ACETYLSALICYLIC ACID;ASCORBIC ACID]) taken for cardiac disorder; atorvastatin (ATORVASTATIN) taken for blood cholesterol abnormal; amlodipine (AMLODIPINE) taken for blood pressure abnormal and multivitamins. The first shot knocked him on his butt. He slept for two weeks then he started to pass blood clots in his urine. He read that the vaccine can cause clotting and he doesn't know if that might have caused the clots right after the shot. He just needs someone to hold his hand about getting the second shot. He has to leave in a couple of hours to get it. He was asking do we see a pattern where people have had a bad first reaction with the first shot and they don't have a bad a reaction the second time around. He clarified he received the first dose of the Pfizer COVID 19 vaccine on 18Feb2021 at 1600 in the right arm. He was fine until Saturday (20Feb2021) when he woke up nauseous; really tired; could not get out of bed; and then really didn't do anything for two weeks. He added he couldn't stay awake even sitting up in his chair. He couldn't eat anything because the sight or smell of food made him gag, even in the grocery store. He added he also noticed he started to get the blood clots in his urine the second day after the shot (20Feb2021). On 19Feb2021, he mentioned he had a bruise on his arm about the size of a half dollar where he got the shot and he usually does not bruise. He stated he felt like he had all the symptoms of COVID. All of these symptoms lasted two weeks. When he finally felt better the only thing he wanted to eat was a burger and fries. He is still bleeding but it is not clotting anymore. The clots only lasted about a week. He also thought he was having a heart attack, but was too tired to go to the hospital. After speaking to his physician/specialist, they encouraged him to go ahead and get the 2nd dose. The patient would like to know whether the benefits outweigh the risks for him to receive the 2nd dose of the Pfizer covid vaccine based on his medical history. The patient would like to know whether one dose of the Pfizer covid vaccine provides some protection. The patient was asking whether he might die from receiving the 2nd dose of the Pfizer covid vaccine. The outcome of the events heart attack was unknown; events bruise on his arm about the size of a half dollar where he got the shot and blood clot in urine was recovered on 27Feb2021
COVID19 VACCINE	PFIZER\BIONTECH	1143485-1	Unknown	1 day	woke up with a blood clot lying in her mouth; This is a spontaneous report from a contactable consumer (patient's parent). A 23-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 13Mar2021 (Batch/Lot number was not reported) as single dose for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient received her first dose of the Pfizer COVID-19 vaccine yesterday (13Mar2021), and this morning (14Mar2021) she woke up with a blood clot lying in her mouth. The reporter wanted to know if this side effect had been reported or of this could be associated with the Pfizer COVID-19 vaccine. The outcome of event was unknown. Information on the lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1147267-1	65+ years	1 day	Had vaccine about 9:35 am on 3/20/21. In the middle of the night about 2:30 am 3/21/21 He should signs of paralysis on right side of his body and was not able to walk. Went to the emergency room on 3/21/21. Admitted to the hospital. MRI was done about 8:00 pm on 3/21/21 and results were blood clot on left side of the brain caused a stroke. Paralysis of right side of his body and changes in speech. Transferred Rehabilitation Hospital 3/24/21. Possibility of second stroke, and another scan done 3/29/21. Waiting for results
COVID19 VACCINE	PFIZER\BIONTECH	1155130-1	60-64 years	1 day	Deep vein Thrombosis cot, followed 2 days later by multiple blood clots in her lungs.

COVID19 VACCINE	PFIZER\BIONTECH	1156434-1	60-64 years	1 day	acute left leg pain and swelling 15 hour after vaccination with subsequent same day ER visit and ultrasound diagnosis of acute left leg DVT (blood clot) diagnosed.
COVID19 VACCINE	PFIZER\BIONTECH	1157256-1	18-29 years	1 day	3/23 developed chest tightness with shortness of breath 3/26 dry cough 3/30 +D-Dimer 14,103. CT showing pulmonary emboli right main pulmonary artery and left lower lobar artery.
COVID19 VACCINE	PFIZER\BIONTECH	1160725-1	30-39 years	1 day	1/19/21 - received vaccine around 6:45 pm 1/20/21 - woke up noticing shortness of breath with minimal activity. Monitored, but symptom progressed throughout the day 1/21/21 - woke up with extreme fatigue and more shortness of breath. Unable to walk at all without gasping. Self-monitored with home pulse ox. O2 down in mid 80s and pulse up to 150 with minimal activity 1/22/21 - woke up with worse shortness of breath symptoms. Had husband drive me to the ER and was admitted for 4 days with bilateral moderate to extensive pulmonary emboli
COVID19 VACCINE	PFIZER\BIONTECH	1162111-1	65+ years	1 day	microemboli.; some splinter hemorrhages; erythema and tenderness progressively over weeks of all her finger pads; erythema and tenderness progressively over weeks of all her finger pads; crop is elevated; This is a spontaneous report from a contactable physician. A 67-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 intramuscular, administered in left arm on 25Feb2021 12:00 (Lot number was not reported) as single dose for covid-19 immunization at age 67 years old. The vaccine was given in a Pharmacy or Drug Store. Medical history included APLA, hypothyroid, obesity, and allergies. The patient was not pregnant. No covid prior to vaccination and was not tested for covid post vaccination. Concomitant medications included warfarin sodium (COUMADIN); levothyroxine sodium (SYNTHROID); cetirizine hydrochloride (ZYRTEC); all taken for unspecified indications, start and stop date were not reported. No other vaccines administered in four weeks. The patient previously took erythromycin and PCP and experienced allergies to both. The patient previously received the first dose of bnt162b2 intramuscular in left arm on 04Feb2021 12:00 PM (at age 67 years old) for covid-19 immunisation. The patient with APLA on coumadin 1-2 days after receiving the vaccine developed erythema and tenderness progressively over weeks of all her finger pads, crop is elevated (as reported) and some splinter hemorrhages suspect microemboli. Just to left hand, systemically well. The adverse events occurred on 26Feb2021 12:00 PM. The AE resulted in: Doctor or other healthcare professional office/clinic visit. No treatment was given to patient for the events. The patient had not recovered from the events. Information on the lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1164774-1	65+ years	1 day	Pt. presented to ED on 5 Mar, day after vaccine with SOB and CT showed PE. Discharged from hospital on 6 March
COVID19 VACCINE	PFIZER\BIONTECH	1169566-1	65+ years	1 day	formation of a blood clot in right calf
COVID19 VACCINE	PFIZER\BIONTECH	1170918-1	60-64 years	1 day	after receiving my second pfizer vaccine, i blacked out, broke my nose, and had a concussion. I had maxillofacial surgery the next day. 5 weeks later, i developed DVT, and now have pulmonary embolisms.
COVID19 VACCINE	PFIZER\BIONTECH	1172285-1	60-64 years	1 day	patient had headache within the first 15 minutes after administration and was found to be positive for dural venous sinus thrombosis with unknown etiology
COVID19 VACCINE	PFIZER\BIONTECH	1177745-1	65+ years	1 day	Pulmonary embolisms in both lungs
COVID19 VACCINE	PFIZER\BIONTECH	1179308-1	50-59 years	1 day	Thrombocytopenia; Blood clots in brain; This is a spontaneous report from a contactable consumer (patient). A 53-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) solution for injection, dose 1 via an unspecified route of administration, administered in left arm on 29Mar2021 13:00 (Batch/Lot Number: EN6206) as single dose for Covid-19 immunisation. The patient's medical history and concomitant medications were not reported. On 30Mar2021, patient developed thrombocytopenia and was brought to emergency room/department or urgent care leading to admission, surgery was performed (mechanical thrombectomy) on 30Mar2021 at 10am to address blood clots in the brain. Patient was currently in ICU until he fully recovered. Patient was hospitalized in Mar2021 for 2 days. The events were reported as life-threatening and have caused disability. Outcome of the events was unknown. Information on lot/batch number has been available. Additional information has been requested.

COVID19 VACCINE	PFIZER\BIONTECH	1183325-1	60-64 years	1 day	Difficult breathing, hoarseness, shortness of breath, chest pain
COVID19 VACCINE	PFIZER\BIONTECH	1183985-1	Unknown	1 day	Fluid in his bottom right lobe of his lung where the cancer is; Inflammation in the bottom of his lung; in lower right lobe of lung; Blood pressure isn't stable; going up and down; Blood pressure issues; Exhausted; fatigue; Trying to control his blood pressure and his pulse issues, pulse incomplete; Muscle weakness was severely progressing; Bad reaction to the Covid vaccine; Blood clot on his lung; Raspy voice; the patient had been sick; Moderate headaches; Passed away; This is a spontaneous report from a contactable consumer (patient) based on the information received by Pfizer from Pharmaceuticals (Manufacturer control number 2020CAT00505). A 74-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date at single dose for COVID-19 immunisation. Co-suspect drug included amifampridine phosphate (FIRDAPSE) orally, from 18Sep2020 to an unspecified date at 10 mg thrice daily, from 02Oct2020 to an unspecified date at 20 mg thrice daily, for Lambert-Eaton myasthenic syndrome. Medical history included Lambert-Eaton myasthenic syndrome (he could not walk without FIRDAPSE), migraine ever since he was a kid, small cell lung cancer (in liver and lymph nodes; brain metastases), metastases to liver, metastases to lymph nodes, radiotherapy of his head and lung for his cancer, gait disturbance from an unknown date and unknown if ongoing, muscular weakness from an unknown date and unknown if ongoing. Concomitant medications included pantoprazole, acetylsalicylic acid (ASPIRIN (E.C.), furosemide. The patient experienced blood clot on his lung in Jan2021 with outcome of unknown, fluid in his bottom right lobe of his lung where the cancer was on an unspecified date with outcome of not recovered, inflammation in the bottom of his lung; in lower right lobe of lung on an unspecified date with outcome of not recovered, raspy voice in 2021 with outcome of recovered, blood pressure not stable; going up and down; blood pressure issues on an unspecified date with outcome of not recovered, exhausted; fatigue on an unspecified date with outcome of not recovered, sick in 2021 with outcome of unknown, trying to control his blood pressure and his pulse issues, pulse incomplete on an unspecified date with outcome of unknown, moderate headaches from 19Sep2020 with outcome of recovered, muscle weakness severely progressing on an unspecified date with outcome of unknown, 10 mg 3 times a day wasn't enough (therapeutic product effect incomplete), on an unspecified date with outcome of unknown, he'd switch and do a couple doses of 15 mg and it was better but not enough (intentional product use issue) on an unspecified date with outcome of unknown, after he received the COVID vaccine, he experienced a bad reaction (unspecified) on an unspecified date with outcome of unknown. The events were reported as serious as involved hospitalization. The patient passed away on an unspecified date in Feb2021. It was not reported if an autopsy was performed. The clinical course of the events included the following information. On 21Sep2020, a spontaneous report was received from a consumer, via a company representative, regarding a 74-year-old male who was being treated with FIRDAPSE 10 MG (amifampridine). On 22Sep2020, additional information was received from a consumer. On 02Oct2020, additional information was received from a consumer and chemotherapy was added as a co-suspect. On 01Feb2021, additional information was received from a consumer via a company representative. On 09Feb2021, additional information was received from a consumer, and this case was determined to be the master case for cases

COVID19 VACCINE	PFIZER\BIONTECH	1191810-1	50-59 years	1 day	they had a ultrasound done and found out I had a number of clots in that position; a sore Leg, Upper part of the left calf 2 inches below the knee on the backside; This is a spontaneous report from a contactable consumer. A 55-years-old male patient received bnt162b2 (PFIZER-BIONTECH mRNA COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 18Mar2021 15:00 (Batch/Lot Number: En6207) as SINGLE DOSE for covid-19 immunisation. Medical history included Treatable Acid reflex, anxiety and mild depression. Concomitant medications included omeprazole, buspirone and alprazolam for unspecified indication. Patient had the Covid shot on 18Mar2021 at about 3 PM the next morning (on 19Mar2021 06:00) patient woke up with a sore Leg, Upper part of the left calf 2 inches below the knee on the backside. After it did not go away, he went to the doctor then they had a ultrasound done and found out he had a number of clots in that position. Treatment received for the adverse event includes they put patient on a blood thinner. Prior to vaccination, was the patient did not diagnose with COVID-19. Since the vaccination, the patient has been tested for COVID-19. patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 24Mar2021. Covid test post vaccination done via nasal Swab, They had the results in 15 minutes, covid test result Negative, ultrasound scan: clots in that position on 19Mar2021 found out, had a number of clots in that position. Outcome of the events was recovering.
COVID19 VACCINE	PFIZER\BIONTECH	1191817-1	50-59 years	1 day	Developed Left lower extremity DVT 24 hours after vaccine; This is a spontaneous report from a non-contactable Physician. A 59-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot number not provided), via an unknown route, on 24Mar2021 (at the age of 59-year-old) at a single dose for COVID-19 immunisation. Relevant medical history included hypertension (HTN), diabetes mellitus (DM) and hyperlipidemia (HLD). The patient did not have history of deep vein thrombosis (DVT) and no other risk factors. The patient was not diagnosed with COVID-19 before vaccination. No relevant concomitant medications were provided. She developed left lower extremity DVT 24 hours after vaccine, on 25Mar2021. The event required emergency room visit. The patient was treated with an anticoagulation therapy. Post vaccination COVID-19 test was not done. The outcome of the event was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on the information currently available, the event deep vein thrombosis was most likely due to the patient's underlying hypertension, diabetes mellitus and hyperlipidemia. However a possible contributory role of vaccine BNT162B2 to the event can not be totally excluded. Case will be re-assessed upon the additional information provided. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1198435-1	60-64 years	1 day	12 hours after receiving 2nd vaccine (4-5-21) I started throwing up through Tuesday 4-6-21. Then on 4-7-21, my left leg calf was very sore and hard for me to walk, Got worse, so on 4-9-21 went into Urgent care and through a vascular ultra sound determined I had a very Large blood clot in my calf. (ACUTE THROMBOSIS OF THE LEFT PROXIMAL PERONEAL VEIN)
COVID19 VACCINE	PFIZER\BIONTECH	1198798-1	60-64 years	1 day	Began feeling unwell, had urinary urgency, and was itching shortly after 2nd dose of Pfizer COVID-19, then found obtunded due to pulmonary embolus resulting in death within 24 hours of receiving 2nd dose
COVID19 VACCINE	PFIZER\BIONTECH	1206305-1	40-49 years	1 day	Severe headaches and ear pain on right side of ear. She thought she was getting migraines (but hadn't suffered from migraines in over 20 years). Went to doctor on 3/3 due to severe pain. No thoughts of what it could be. Continued headaches with no relief. Received migraine shots in hip on night of 3/11. Severe stroke on 3/13. Should not be at risk for a stroke and does not have any typical factors for being at risk. Has been in hospital and in-patient rehab since. Has a fully occluded clot in her right ICA.
COVID19 VACCINE	PFIZER\BIONTECH	1207638-1	50-59 years	1 day	Pulmonary Embolism (blood clot)
COVID19 VACCINE	PFIZER\BIONTECH	1209389-1	50-59 years	1 day	PE in both lungs. Needed an ER visit 5 days after vaccination

COVID19 VACCINE	PFIZER\BIONTECH	1209859-1	60-64 years	1 day	Slight headache that day (4/1). The next day (4/2), weakness in left leg and arm. On 4/3 went to ER, admitted to NeuroScience ICU. Diagnosed with small blood clot and small bleed in brain— dural venous sinus thrombosis. The neurology team said this was very unusual and very rare in this part of brain—where the blood flows back to the heart from the brain. They did alot of tests on every part of my body looking for the cause and found nothing. They think it was vacine induced and repoted it to the CDC. Left leg and arm weakness remains with no changes yet. Now taking blood thinner and doing physical therapy
COVID19 VACCINE	PFIZER\BIONTECH	1210794-1	40-49 years	1 day	Cold sweats starting Thursday evening, Friday sweating at night, and Saturday morning ~6:00 am with chest pain and sweats. Pain intensified and brought to Urgent Care at 8 am where an EKG was completed and showed signs of a heart attack. Was rushed to Hospital Emergency room. Admitted and examined. Completed an angiogram and noted that there was a blood clot that appeared to dissolve. Troponin levels were high showing damage to the left artery. Spent the night in the hospital. Prescribed medication for cholesterol, blood thinners, and seeing a cardiologist.
COVID19 VACCINE	PFIZER\BIONTECH	1211381-1	40-49 years	1 day	patient developed chest pain, right rib pain and dyspnea 1 day following vaccine
COVID19 VACCINE	PFIZER\BIONTECH	1212270-1	30-39 years	1 day	The patient was reportedly in her USOH until she received the first dose of the Pfizer vaccine on 1/4. She woke up the following morning with a terrible headache and photophobia, later in the day developing myalgias and generalized weakness, followed by possible fever (did not take home temp). She describes the headache as a throbbing holocranial ache that is worse if she bends down She states the headache never really went away fully over the ensuing days, and she did begin to notice blurred vision in her right eye; she eventually presented to Medical Center on 1/9, where she was tested for COVID-19 and found to be negative - her symptoms were attributed to a vaccine reaction and she was sent home. She continued to have a terrible headache and blurred vision, and so returned to Medical Center on 1/12. She then presented to another Hospital she was admitted for frequent falls in the context of elevated blood pressure. Workup there included a head CT, which was unremarkable. She was discharged with home PT. On the day of presentation, she fell at physical therapy. Now with pain from R knee down. No numbness in the leg. States leg twisted when she fell. No head strike or LOC. States pain with attempted ambulation. This resulted in her presentation to the ED at a Medical Center on 1/27/21. On evaluation, she endorsed a headache, holocranial, throbbing, 5-6/10 (has been 10/10). Denies frank positional component. Not worse at any certain time of day. +Blurred vision, worse on the R. +photophobia, not phonophobia. Also complains of pulsatile tinnitus happening almost daily, R-sided, worse when bending down. Denies nausea or vomiting. Denies neck pain or stiffness. Exam was notable for significant peripheral vision loss in R>L eye and bilateral papilledema. She was seen by ophthalmology with documentation of formal visual field testing (reports included). MRV with filling defects in straight, sagittal, and R transverse sinuses; MRI without FLARE changes, reassuring for no obstruction and/or infarct.
COVID19 VACCINE	PFIZER\BIONTECH	1214050-1	50-59 years	1 day	developed chest pain and shortness of breath 12 hours after vaccination and went to ED and hospitalized with PE and DVT and now on xarelto
COVID19 VACCINE	PFIZER\BIONTECH	1214953-1	60-64 years	1 day	Acute Pulmonary Embolism-Bilateral , Hypertensive Crisis

COVID19 VACCINE	PFIZER\BIONTECH	1224608-1	50-59 years	1 day	<p>tip of left ring finger turned white and numb/finger was completely white and the rest of her hands were blue and red and white and yellow; tip of left ring finger turned white and numb; her finger felt funny; Reynauds phenomenon; sore arm; fever; chills; headache; swollen lymph node in the armpit of the arm she got her Covid 19 vaccine in; swollen lymph node started with a sharp pain and it's very sore; left foot, it was pulsing and throbbing all night; feet were modeled red, blue; feet were modeled red, blue; very sick; needed her glasses trying to give her primary care doctor's phone number; has something like gout in her foot; The swollen lymph node started with a sharp pain and could be a blood clot as far as she knows; This is a spontaneous report from a contactable consumer (patient) via the medical information team. A 57-year-old female patient received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot: EW0150; expiry: 31Jul2021), via an unspecified route of administration in left arm on 31Mar2021 01:30 as single dose for covid-19 immunisation. The vaccination facility type was a warehouse. The vaccine was not administered at a military facility. No previous immunization with the Pfizer vaccine considered as suspect. No vaccines administered on same date with the Pfizer vaccine considered as suspect. No prior vaccinations (within 4 weeks) and no following prior vaccinations. Medical history included covid-19 in Nov2020. The patient had no concomitant medications. The patient had the first dose of bnt162b2 on 31Mar2021 and 12 hours later (on 01Apr2021), sore arm, fever, chills and headache. Got a swollen lymph node in armpit, same arm as injection left side, today tip of left ring finger turned white and numb. She thinks it was Reynauds phenomenon. The patient called and told nurse in her doctor's office and they said if it was painful, it could be a pain clot. It was painful at first, that lymph node started 24 hours later with a sharp pain, and then she just assumed it could be a lymph node. Swollen lymph node started with a sharp pain and it was very sore. The nurse told the patient to call Pfizer. The patient was fine until the tip of her finger happened. The patient said If it was painful it could be a blood clot, would need an x ray and asked if did the shot cause this. The complete ring finger left hand, the patient looked it up and it said it could happen to her feet and she looked, and her feet were modeled red, blue it was bizarre. Never happened before. The patient was not happy about getting the vaccine, she already had covid in November of last year (2020). The patient wouldn't have called if it wasn't for her finger. Not just her feet, her hands got like this too. The patient didn't want to get the second shot. The patient asked if there was any information or mandate on timing information for the second dose, should she needed to postpone it. The patient asked if what was the efficacy after first dose as she felt like she was immune because she had the virus and now the vaccine. She was very hesitant to get the Covid 19 vaccine. She thinks her body created Covid 19 antibodies. A couple days ago she was very sick. The swollen lymph node started with a sharp pain and could be a blood clot as far as she knows (in 2021). Even putting on deodorant she can tell it's there, it was very sore and there's a lump. Today (on 01Apr2021), she noticed the tip of her finger got white it was numb. She looked it up online and she thinks it was Reynaud's phenomenon. She has a picture if Pfizer needed it. The finger was on the same arm that she received her vaccine in. It was the ring finger on left hand. Once it started happening her finger felt funny and</p>
COVID19 VACCINE	PFIZER\BIONTECH	1224928-1	40-49 years	1 day	<p>Blood clot DVT in left leg.; Blood clot DVT in left leg.; This is a spontaneous report from a contactable consumer. A 48-year-old non -pregnant female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), at the age of 48 years, via an unspecified route of administration, administered in the left arm on 01Apr2021 10:45 (Batch/Lot number was not reported) as a single dose for covid-19 immunization. The patient has no medical history. Patient has not had Covid prior to vaccination. The patient has no known allergies. The patient's concomitant medications were not reported. The patient experienced blood clot DVT in left leg on 02Apr2021 at 09:00. Treatment for the event includes blood thinners. It was reported that the AE resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Life threatening illness (immediate risk of death from the event). The patient underwent lab tests and procedures which included nasal swab for covid test on 02Apr2021 which had a negative result. The outcome of the event was not recovered. Information about Lot/batch number is requested.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1227272-1	65+ years	1 day	<p>massive stroke; massive blood clot in brain next day; This is a spontaneous report from a contactable healthcare professional. An 83-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 08Mar2021 10:00 (Batch/Lot number was not reported) as a single dose for COVID-19 immunization. There were no medical history and concomitant medications. Patient is not pregnant at the time of vaccination. Patient did not receive any other vaccines within 4 weeks and no other medications within two weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. Patient has not been tested for COVID-19 since the vaccination. Patient has no known allergies. On 09Mar2021 19:00, patient had massive blood clot in brain and stroke. AE resulted in: emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event). Patient died on 13Mar2021 with cause of death: massive stroke. Outcome of the event ""massive blood clot in brain next day"" was unknown. Autopsy was not performed. Treatment received for AEs include anticoagulant. Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Stroke and Thrombosis cerebral cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: massive stroke""</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1254796-1	50-59 years	1 day	<p>Blood clots in right leg below knee; he passed out from pain; pain in his right knee; he couldn't bend his knee at all; knee was swollen; couldn't walk/limping around; his knee more stiff; This is a spontaneous report from a contactable consumer (patient). A 53-year-old male patient received the first dose of BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot number: EN6206), via an unspecified route of administration, administered in the right arm on 21Mar2021 at 10:00 as a single dose for COVID-19 immunization. Medical history included ongoing Factor V Leiden heterozygous, allergies to mushrooms from an unknown date and unknown if ongoing and a torn meniscus in his right knee and he had surgery 3 to 4 years ago. The patient's concomitant medications were not reported. The patient previously took Cephalexin and Percocet and experienced allergies. The patient did not have COVID prior to vaccination and has not been tested post vaccination. On 22Mar2021 at night around 2:30AM, the patient woke up and started walking to the bathroom and he passed out from pain. He had pain in his right knee. He thought he had torn his knee again. He had surgery 3 or 4 years ago for a torn meniscus in his right knee and he thought he had torn his meniscus again. He passed out, his wife found him and he went back to bed. In the morning, his knee was still very very sore, he couldn't bend his knee at all. He took an Advil between 6:30AM and 8:00AM. He hadn't taken any medications prior to the COVID-19 vaccine. His knee was swollen but the pain was manageable. He couldn't walk, he was on crutches for about 24 hours then the swelling started coming down and he put a brace on his knee. He could then walk without the crutches but it was still painful. The next day he had pain in the back of his knee. He thought the pain was caused because he had put the brace on and had been using the crutches. Like he had made his knee more stiff from not using it. He was limping around and the pain was bearable. At that point, the pain was maybe a 4 on a scale of 1-10 where his pain had been a 9 on a scale of 1-10. He took another Advil and he realized the pain in the back of his knee wasn't going away. He went to see his family doctor and his doctor was able to get him in that same day for an ultrasound. The ultrasound showed 2 blood clots behind his right knee. The patient had blood clots in right leg below knee. The week of the report, he got an appointment with a hematologist. The hematologist reviewed his case and the doctor isn't 100% sure the blood clots were from the Pfizer COVID-19 vaccine but the doctor isn't ruling it out either because it happened within 24 hours of receiving his first COVID-19 dose. He hadn't done anything strenuous before getting the COVID-19 vaccine, nothing that he thinks would have caused the blood clots. He would like to add, what he thinks is relevant, is that he is positive for Factor V. He reports he has one copy and Factor V only impacts about 3% of the population. The hematologist thought that he might be prone to developing blood clots. The hematologist reports that he has had patients who have had the COVID-19 virus who have developed blood clots. Maybe it's possible that the COVID-19 antibodies were trying to build up his immune system to COVID-19 and it created something similar to having the COVID-19 virus. If he is predisposed to blood clots then the COVID-19 vaccine may have precipitated the blood clots. His second COVID-19 vaccine is scheduled for Sunday, 11Apr2021. He had talked to both his family doctor and his hematologist and they both thought he should be ok in getting the second COVID-19 vaccine. He was prescribed blood thinners. If the</p>
COVID19 VACCINE	PFIZER\BIONTECH	1261778-1	18-29 years	1 day	<p>Swelling underneath my left arm pit which may be a possible blood clot; Swelling underneath my left arm pit which may be a possible blood clot; This is a spontaneous report from a contactable consumer (patient). A 26-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number and expiration date were not reported) on the left arm on 08Apr2021 (16:15) as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 09Apr2021 (05:45), the patient had swelling underneath my left armpit which may be a possible blood clot. The patient did not receive any treatment for the reported events. The outcome of the events was not recovered. The patient did not have COVID-19 prior to vaccination, and had not been tested post-vaccination. Information on the lot/batch number has been requested.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1261799-1	40-49 years	1 day	I was diagnosed with a blood clot in my right leg; This is a spontaneous report from a contactable consumer (patient). A 49-year-old female patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration, administered in right arm on 03Mar2021 15:45 (Lot Number: EN6202), at the age of 49-years at vaccination, as SINGLE DOSE for covid-19 immunisation. Medical history included none. The patient is not pregnant at the time of vaccination. The patient received dose 1 of the vaccine on 10Feb2021, lot number: EM9810, on 10Feb2021 03:45 PM at right arm. The patient did not have COVID-19 prior vaccination. The patient's concomitant medications were not reported. On 04Mar2021 12:00 AM, patient was diagnosed with a blood clot in her right leg. The event required emergency room visit. The patient was put on Xarelto, a blood thinner for clots. The patient has not been tested for COVID-19 post vaccination. The outcome of the event was unknown.
COVID19 VACCINE	PFIZER\BIONTECH	1265944-1	40-49 years	1 day	DVT; PE; This is a spontaneous report from a contactable physician. A 42-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly in the left arm, on 28Jan2021 (at the age of 42-years-old) as a single dose for COVID-19 immunisation. Medical history included hypertension (HTN) and fibroids. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient had no known allergies. Concomitant medication included amlodipine besilate (MANUFACTURER UNKNOWN). The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), intramuscularly in the right arm, on 07Jan2021 (at the age of 42-years-old) for COVID-19 immunisation. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced deep vein thrombosis (DVT) and pulmonary embolism (PE) on 29Jan2021, which caused hospitalization for 5 days from an unspecified date to an unspecified date. Therapeutic measures were taken as a result of the events, which included direct oral anticoagulants (DOAC). The clinical outcome of DVT and PE was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.; Sender's Comments: Based on the information currently available, a possible contributory role of the suspect vaccine BNT162B2 or comirnaty in triggering the onset of Deepvein thrombosis,pulmonary embolism cannot be excluded.But also consider relevant medical history of hypertension and fibroids tendency to form blood clots and concomitant medications also have possible contributory role. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID19 VACCINE	PFIZER\BIONTECH	1265991-1	65+ years	1 day	<p>Blood clot in lung; Shortness of breath; Felt tired; Slight headache; This is a spontaneous report from a contactable consumer (patient). A 79-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: EN6201), dose 2 intramuscular, administered in Arm Right (also reported as ""injected intramuscularly in right arm"" ) on 23Feb2021 13:00 (at the age of 79years) as single dose for Covid-19 immunization. The patient received the first dose of BNT162B2 (lot number: EL8982) on 02Feb2021 (at the age of 79years) for Covid-19 immunization. Medical history included high blood pressure (diagnosed prior to 10 years ago), respiratory illness, genetic/chromosomal abnormalities, endocrine abnormalities including diabetes, diagnosed allergies, compromised immune status, and obesity (Little on the heavy side but she does not think she is obese); all from an unknown date and unknown if ongoing. Concomitant medication included lisinopril taken for high blood pressure at 20 mg once daily, started at least 10 years ago. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. It was reported that the patient had received the two doses, she had shortness of breath in the morning around 08:30 on 08Mar2021 and went to her doctor. They did blood work and she was put in the hospital because the doctor found out she had blood clots in her lungs (11Mar2021, 13:00). The patient was hospitalized for blood clot in lung from 11Mar2021 to 13Mar2021. She doesn't know if it came from the vaccine or not. She was sent home on Eliquis for 6 months to get blood clots from her lungs. She also has oxygen for when she needs it and mostly for when she is ambulatory. It was further clarified that when she went to her doctor's office, they did blood work. When they got results, they called her at home and told her that she had to call the ambulance and go the hospital in the ambulance, so she did; Ambulance to ER (hospital) on 11Mar2021. There was also a problem with the left ventricle of her heart (12 Mar2021 12:30). She stated whichever part pumps blood into the pulmonary vein, something is wrong there. She was going to have an echocardiogram to check that out again on 29Apr2021. She does not know the outcome of that yet until she gets that done. They gave her Eliquis as a blood thinner and oxygen. She has not really needed the oxygen around the house. But if she goes outside, she may. She took it to the grocery store with her and if she needed it, she used it. She also had a headache after second dose on 24Feb2021 09:00. She felt tired on 24Feb2021 21:00 and stuff (as reported). The outcome of event blood clot in lung was unknown; the outcome of other events was recovering.""</p>
COVID19 VACCINE	PFIZER\BIONTECH	1266361-1	65+ years	1 day	<p>April 22, 2021 morning my auntie got her first dose of Pfizer vaccine. She happily shared here vaccine experience with family member and relative. April 23 morning, she told us she has severe abdominal pain, has the need to have a bowel movement, but she was defecated. She also told us that she vomit couple times already, then she has no more energy to talk. She got into the hospital and she was announced death right after midnight at 12:04 April 25th. Reason of death given is ""septic shock secondary to ischemic bowel &amp; intra-abdominal sepsis"". But it is the blood clots issue that is causing it. I was told that after my auntie got into hospital the very next day after Pfizer vaccine, hospital later found out that my auntie has blood blockage issue that is causing blood couldn't flow to her intestines. The acid in her blood was very high, 6+. After more than 6 hours without blood to her intestines, her intestines tissues start dying and turned black color. Doctor found out about this at the night of April 23, 2021 nighttime. April 22, 2021 morning is the day my auntie got her Pfizer covid vaccine. There is a very high chances of the Pfizer vaccine is causing the blood clots that lead to blood blockages.""</p>

COVID19 VACCINE	PFIZER\BIONTECH	1269502-1	30-39 years	1 day	<p>Caller states she was not due for her monthly menstrual period for another week, so she found, passing the clot, odd.; Blot clot/Very big blood clot, that passed out of body; Fever, of 102; Sore arm; This is a spontaneous report from a contactable Other HCP (patient). A 35-years-old female patient (no pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Right on 29Mar2021 09:00 (Lot Number: ER2613) as single dose for covid-19 immunisation. Medical history included ongoing asthma , contraception. Concomitant medication included ethinylestradiol, norgestimate (SPRINTEC) taken for contraception from an unspecified start date and ongoing. The patient previously took bactrim and experienced drug hypersensitivity. The blood clot only was for one day on 31Mar2021, and it was one blood clot. The patient went to the bathroom and it was passed, one time. The patient was not due for her monthly menstrual period for another week, so she found, passing the clot, odd. The patient menstrual period did happen on time and it was normal. The patient was not due for her menstrual period for another week, and she takes birth control. The patient contacted her Gynecologist, and it was confirmed that she was not pregnant, and states her menstrual period happened on time. The clot did not happen again. The patient had Fever, of 102 on 30Mar2021, the temperature resolved in a day. The patient took Aleve, drank a lot of water and napped, reclarifies, and the temperature improved. The patient experienced sore arm on 30Mar2021. The outcome of event Clot blood was recovered on 31Mar2021; outcome of event Fever was recovered on 30Mar2021; outcome of event Sore arm was recovered on 01Apr2021, outcome of other event was unknown. No other vaccine in four weeks; No covid prior vaccination; No covid tested post vaccination.; Sender's Comments: Based on the temporal relationship, A possible contributory role of the suspect product to the development of Thrombosis and Menstrual Disorder cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1278466-1	65+ years	1 day	<p>stroke caused by a blood clot; stroke caused by a blood clot; right arm went completely numb; She is tired; shortness of breath; her eyes were blurry; her head felt like somebody put a spike in it on the right side; sore arm; This is a spontaneous report from a contactable consumer. A 77-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Left on 06Feb2021 13:15 (Lot Number: EM9809) (at age of 77-year-old) as single dose for COVID-19 immunisation. Medical history included colitis ulcerative from Oct2020 (dropped weight, she dropped from 127 pounds to 109 pounds), cardiac disorder, atrial fibrillation, and osteoporosis, all were ongoing. Concomitant medications included carvedilol taken for cardiac disorder, atrial fibrillation from an unspecified start date and ongoing; cyanocobalamin (VITAMIN B12) taken for cardiac disorder from 2018 (reported as has taking it close to 3 years) and ongoing; denosumab (PROLIA) taken for osteoporosis from an unspecified start date and ongoing; ubidecarenone (Q10) taken for cardiac disorder from unknown start date and ongoing; calcium, colecalciferol (CALCIUM + D3) taken for osteoporosis from 2020 (reported as a year ago) and ongoing; influenza vaccine (FLU VACCINE VII) taken for an unspecified indication, start and stop date were not reported, and vitamins NOS (MULTIVITAMIN) from an unspecified start date and ongoing, the patient started taking it when she was a senior in high school and stated because she is not the best eater in the world. There was no prior vaccinations (within 4 weeks). AE(s) following prior vaccinations: The patient stated arm is sore with flu shot and probably did when she was little when she got the loaded shot, the mumps one. She wouldn't remember that because she was little. The patient experienced stroke caused by a blood clot on 20Feb202114:30 with seriousness criteria hospitalization, sore arm on 07Feb2021, and right arm went completely numb, tired, shortness of breath, her eyes were blurry, her head felt like somebody put a spike in it on the right side on an unspecified date. The event stroke caused by a blood clot result in emergency room visit. The patient was hospitalized for stroke caused by a blood clot from 23Feb2021 to 24Feb2021. The patient reported that she received the first dose and she is thankful she got it on 06Feb2021 and the only side effect she had was a sore arm. Stated on 20Feb2021 she had a stroke caused by a blood clot obviously, she ended up in the hospital. She didn't think at the time, doesn't fault the physicians that took care of her. She didn't think it was related and her eldest son thought it was related. The patient stated they thought it was a mild stroke and after they did the C scan the neurosurgeon, while she was lying in the hospital bed, looked at her assistant and said he couldn't believe that she was talking and walking. The patient stated part of it was ignorance on her part, everyone thought it was the left side that numbs, but hers was the right side. Stated she didn't fall, she dropped something and went down to get it and her right arm went completely numb and she couldn't get back up and she tried to push with legs and couldn't get up. Stated all of a sudden her eyes were blurry and then she never gets headaches and her head felt like somebody put a spike in it on the right side, stated it is supposed to affect the left side. stated she has a heart problem. The patient stated she had a sore arm for about a week, lasted for a few days. stated she gets a sore arm with the flu shot. stated when she would roll over to lay on her left side and roll over on</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1278916-1	60-64 years	1 day	<p>DVT blood clot; ankle was still swollen and uncomfortable; ankle was still swollen and uncomfortable/discomfort; nights were the worst for the pain; pulse ox was low; d-dimer was very high; fainted; Fracture of ankle/two fractures on her ankle; severely nauseous; Vomiting; Diarrhea; deathly sick; This is a spontaneous report from a contactable consumer, reporting for herself. A 60-year-old female patient received the first dose of the bnt162b2 (BNT162B2; Lot Number: ER8727), via an unspecified route of administration in the left arm on 26Mar2021 at 14:00 at a single dose for covid-19 immunisation. Medical history included osteoporosis at least 10 years, terrible nausea, mild case of covid from Nov2020 to an unknown date. There were no concomitant medications. The patient previously took alendronate from 2008 to an unknown date and experienced very sick, nausea, diarrhoea and zoledronic acid (RECLAST) from Dec2017 and experienced nausea and vomiting. On 27Mar2021 at 2:00, the patient experienced deathly sick, fainted, fracture of ankle/two fractures on her ankle, severely nauseous, vomiting, and diarrhea. On an unknown date, the patient experienced dvt blood clot, ankle was still swollen and uncomfortable/discomfort, the nights are the worst for the pain, pulse ox was low, and d-dimer was very high. The event, deathly sick, was life-threatening. The clinical course was as follows: the patient had the first dose of the vaccine on 26Mar2021 at 14:00 in the afternoon in her left arm. Twelve hours after the first dose, later in the night about 02:00 AM she woke up deathly sick; and severely nauseous. She remembered she was going to the bathroom then she must have fainted because they were taking her to the hospital. She went to the ER and they found she had a fractured ankle. She was not admitted to the hospital. She was in the ER from about 03:00 AM to noon the next day. There must have been something in there; she knew there must be something in the vaccine because of her reaction. Adds a few years ago, something like this happened before. She had osteoporosis and had similar reactions with other products she had tried for osteoporosis; she had terrible nausea. The other products she tried included: in 2008 she took alendronate, it made her very sick but not as severe as this time, she never fainted. She had nausea and diarrhea. Then in Dec2017 she had zoledronic acid. She went for an infusion at the hospital then went shopping, and was fine until the early morning, when she woke up with nausea and vomiting. In the ambulance, they gave her ondasetron (ZOFRAN) for the nausea so the vomiting stopped. With regard to her ankle, first they thought it was a DVT blood clot. They did the xray and saw actually two fractures on her ankle but she does not need surgery. She saw the orthopedic doctor the other day and he said her ankle was healing but she still will have no weight bearing for 6 weeks and she was in a boot. Adds her ankle was still swollen and uncomfortable. She hated to take medications and they gave her oxy but she didn't want to take it. She was taking ibuprofen but that messed up her stomach. The nights are the worst for the pain and discomfort. Doctor at the hospital and primary care agreed she should not have the second dose. She did have mild case of COVID in Nov2020 and they are hoping she had antibodies from the infection and the first dose. Her primary care doctor was reviewing the blood work she had done at the hospital and told her they were surprised the hospital didn't admit her for observation because her pulse ox was low and there was another test that she was questioning</p>
COVID19 VACCINE	PFIZER\BIONTECH	1278921-1	50-59 years	1 day	<p>diagnosed with DVT/slight pain in right calf/severe pain in right calf (unable to weight bear); This is a spontaneous report from a contactable consumer (patient). A 52-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: ER8737), via an unspecified route of administration, administered in arm left on 02Apr2021 at 10:45 (at the age of 52-years-old) as a single dose for COVID-19 immunisation. Medical history included retinoblastoma, menorrhagia and fibroids from an unknown date and unknown if ongoing. Concomitant medications included ethinylestradiol, norgestrel (OGESTREL-28) taken for menorrhagia, uterine leiomyoma; iron taken for an unspecified indication, start and stop dates for both were not reported. On 03Apr2021, the patient woke up with slight pain in right calf. On 04Apr2021, she woke up with severe pain in right calf (unable to weight bear), then went to Urgent Care and was diagnosed with deep vein thrombosis (DVT) 7cm. Started apixaban (ELIQUIS) for 3 months, stopped low norgestrel. Therapeutic measures were taken as a result of the event. The outcome of the event was recovering.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1284857-1	65+ years	1 day	small blood clot in brain; This is a spontaneous report from a contactable consumer (patient). A 86-year-old male patient received the second dose of bnt162b2, via an unspecified route of administration on 08Apr2021 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. Medical history included Type two diabetes b, covid prior vaccination in 2021, blood clot in lung. Concomitant medication included exenatide (BYETTA). The patient previously received the first dose of bnt162b2, via an unspecified route of administration on unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient experienced small blood clot in brain on 09Apr2021. The event resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization (4 days), Life threatening illness (immediate risk of death from the event), Disability or permanent damage. Patient received the treatment Heparin for event. Covid test post vaccination (Blood test) was negative on 12Apr2021. The outcome of the event was not recovered. Information on Lot/Batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1288363-1	50-59 years	1 day	DVT developed in Right Calf approx 24 hours after the vaccine administration; This is a spontaneous report from a contactable physician. This Physician reported for a 51-year-old male patient who received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 1 intramuscular on 11Mar2021 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. Medical history included kidney stone from an unknown date and unknown if ongoing. There were no concomitant medications. Patient did not receive any vaccine in four weeks. Patient did not receive any vaccine in four weeks. The patient developed DVT in right calf approximately 24 hours after the vaccine administration on 12Mar2021 with outcome of recovering. Therapeutic measures were taken as a result of event included Xarelto. Patient was not tested for covid post vaccination. Information on the lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event DVT cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1288398-1	30-39 years	1 day	superficial thrombophlebitis clot behind left knee; chills; headaches; This is a spontaneous report from a contactable consumer reporting for herself. A 36-years-old female patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration, administered in the Left Arm on 13Apr2021 11:45 (Batch/Lot Number: Ew0162) as single dose for covid-19 immunisation. The patient medical history was not reported. Concomitant medication(s) included hydroxychloroquine (HYDROXYCHLOROQUINE) taken for an unspecified indication, start and stop date were not reported; sertraline hydrochloride (ZOLOFT) taken for an unspecified indication, start and stop date were not reported. The patient experienced superficial thrombophlebitis clot behind left knee on 14Apr2021 with outcome of recovering, chills on 14Apr2021 with outcome of recovering, headaches on 14Apr2021 with outcome of recovering. The reported events were considered serious because caused the patient to visit Emergency room/department or urgent care. Follow up information has been requested. Lot number has already been provided.

COVID19 VACCINE	PFIZER\BIONTECH	1291184-1	40-49 years	1 day	This is a spontaneous report from a contactable consumer (patient's fiance). A 46-year-old male patient received the first dose bnt162b2 (BNT162B2), via an unspecified route of administration, administered in Arm Left on 18Apr2021 11:20 (Lot Number: EW0162) (received at the age of 46-years-old) as SINGLE DOSE for COVID-19 immunisation. Medical history included right knee pain. Concomitant medications were not reported. The patient received the Pfizer 1st shot 18Apr2021 11:20 am. On 19Apr2021, at midnight, he had low grade fever then swelling right leg. On the day of the report, 20Apr2021, he had swelling to both legs. The patient had taken ibuprofen as treatment beside propping legs up. The reporter wanted more information on the swelling and if it's related to taking ibuprofen. It was further reported that the patient experienced severe swelling from the knees down to the calves on both legs on 19Apr2021. He also experienced night sweats, fever, lightheadedness and dizziness on 19Apr2021. They want to know if there are any reports regarding the swelling side effects and if it is from the vaccine. The first dose of the vaccine was given 2 days ago (18Apr2021) and the second dose is due on 09May2021. The patient got his first shot on 18Apr2021 about 11:20am. After about 15 hours he developed swelling in one leg, she later clarified this to be his right leg, and now reports that both of his legs are swollen at the time of report (20Apr2021). She noted that patient told her his legs are not painful. She doesn't know if it's a blood clot or if they needed to go to the hospital. She also wanted to know if there is information about this as a side effects or if other people are having this too. She then reported that the patient started experiencing a fever, profuse sweating, and was spacey about 12 hours after the vaccine, a little after midnight 19Apr2021. She doesn't know if the dehydration made it worse. His fever was low-grade 99.8 degrees and lasted 4 and a half to 5 hours and has now resolved. When asked if patient received any treatment for fever, caller said it was so recent, and that was listed as a common side effect that goes away. Reported the patient drank fluids and she kept an eye on him. Leg swelling was about 15 hours after the vaccine, early morning 19Apr2021. She noted that the swelling in the right leg got bigger and didn't go down, but the left leg did. But today the left was more swollen and more prominent today. She further clarified that the patient takes ibuprofen for pre-existing right knee pain. Caller also reported that the patient propped his legs to alleviate the swelling, it has improved some but the swelling did not go away. The adverse events did not require a visit to the physician office or emergency room. Outcome of the event fever was resolved on 19Apr2021 (lasted 4 and a half to 5 hours); outcome of the event ""severe swelling from the knees down to the calves on both legs"" was not resolved; outcome of the remaining events was unknown.""
COVID19 VACCINE	UNKNOWN MANUFACTURER	1201471-1	50-59 years	1 day	Blood clot on 4/2 in left calf
COVID19 VACCINE	JANSSEN	1112120-1	65+ years	2 days	3/18/21 ER Triage Nurse Note: ""To er via EMS for eval of weakness and dizziness. States he started with sore throat and head congestion last week. Seen PCP Monday 03-15-21. Started amoxil. Took it for 2 days and became dizzy so he quit taking it. Dizziness got worse and came to ER."" 3/18/21 ER HPI: 76 y.o. male who presents with c/o weakness cough and fever for the past seven days. Pt report sx are mod better with rest and worse with movement. Transferred to Hospital, dx: pneumonia dt covid-19 virus""
COVID19 VACCINE	JANSSEN	1112122-1	40-49 years	2 days	Patient was admitted for Multi drug resistant UTI (for which he has been admitted many times before). Was hospitalized for 3 days while awaiting cultures, hemodynamically stable, with no lab abnormalities. On the day of discharge (sensitivities to UTI came back, pt to be discharged on cefepime, had PICC line) pt got up from bed, sat on the edge of the bed and was being given belongings by the nurse, alert and oriented and in a pleasant mood, when suddenly pt grabbed at his chest and stated ""I can't breathe"" and became combative and altered when O2 was attempted to be placed on pt's face; then pt had PEA arrest x3 and unable to achieve ROSC.""
COVID19 VACCINE	JANSSEN	1121937-1	50-59 years	2 days	Bloody nose on March 20th - threw up blood clot. Bloody nose again on March 21st, same clot formed. lasted about 15 minutes each time. Seeing my PC doctor today March 22nd.

COVID19 VACCINE	JANSSEN	1131671-1	50-59 years	2 days	Following the vaccine injection which was provided by the personnel, I have developed minor fainting spells and angina for the past 10 plus days. A large dried blood clot was noted on the first day of my period which occurred on March 16th. I continue to pass large blood clots while I was having my period. I also want to point out that a personnel who gave me an injection was incorrectly injected the vaccine outside of the area of the preferred injection zone. I have reported this event to the supervisor who was on site. I have not yet contacted my health care provider at this time but plan to contact her tomorrow as these symptoms have been persisting.
COVID19 VACCINE	JANSSEN	1182060-1	50-59 years	2 days	Pt hospitalized today 04/08/2021 with chest pain and was found to have a pulmonary embolism.
COVID19 VACCINE	JANSSEN	1183089-1	65+ years	2 days	Friday 3/19 Confusion, did not know her granddaughter, which grandchild she was kept confusing family names. That was very unusual for her. Saturday 3/20 didn't feel good that day, Sunday 3/21 around 3am got up to go to the restroom got very light headed and fell/fainted hitting her head on the night stand and falling to the floor. When EMS arrived she was in A-fib. That had never happened before. No known heart problems.
COVID19 VACCINE	JANSSEN	1200986-1	50-59 years	2 days	Findings in the great saphenous, common femoral, and proximal femoral veins suggesting nonocclusive thrombus.
COVID19 VACCINE	JANSSEN	1201181-1	65+ years	2 days	Leg blood clot that traveled to my lungs leading to A Pulmonary Embolism
COVID19 VACCINE	JANSSEN	1201996-1	50-59 years	2 days	Shortness of breath started 48 hours post vaccine. Ended up in the ER at hospital on 4/4 with sever shortness of breath and pain in back between shoulder blades. CT and blood work revealed massive Pulmonary Embolism in both lungs and enlarged right ventricle of heart. Pulmonary angiogram was completed, bed rest, ICU and EKOS catheter. Released from hospital on 4/6.
COVID19 VACCINE	JANSSEN	1202072-1	65+ years	2 days	PATIENT WOKE UP AT 12 AM THROWING UP BLOOD AND FEELINGS OF PASSING OUT, 911 WAS CALLED AND AMBULANCE TOOK HER TO HOSPITAL, WHERE THEY DETERMINED IT WAS A STROKE AND MOVED HER TO ANOTHER HOSPITAL, WHERE CURRENTLEY BEING TREATED DETERMINED BLOOD CLOT IN BRAIN. MOST LIKELEY DUE TO VACCINE SHOT.
COVID19 VACCINE	JANSSEN	1202457-1	40-49 years	2 days	Right calf pain similar to previous DVT pain she had experienced in the past. Symptoms starting 4/11/21 day 2 after receiving COVID 19 vaccine.
COVID19 VACCINE	JANSSEN	1204240-1	60-64 years	2 days	Left Leg Superficial Thrombosis.
COVID19 VACCINE	JANSSEN	1206380-1	18-29 years	2 days	On 4/8/2021 I developed a headache after receiving the Johnson and Johnson vaccine. I took the next few days easy, and laid in bed for the majority of the weekend. On 4/10/2021 I left my residence to get dinner and noticed I was short of breath just walking from the building to my car. The shortness of breath worsened over the next few days. On 4/13/2021 I called a clinic and told them I had been short of breath and they directed me to the ER. I arrived to the ER around 2:30 in the afternoon. They ordered a chest x-ray and ran a test to determine if I could have a blood clot. The test came back with results indicating I could have a blood clot, so they did a chest CT and an MRI. The chest CT showed a blood clot in my left pulmonary artery. They prescribed a blood thinner, told me to stop taking oral birth control, and discharged me.
COVID19 VACCINE	JANSSEN	1207508-1	65+ years	2 days	3/5/ 21 Received J & J at facility. 3/7/21 Client had troubles walking and went to Urgent Care. then he went home. He did not have good control (wife described that his legs did not have strength but was able to walk. Symptoms started getting better later that day. 3/15 He got up and he said he was not feeling to good. Chest hurt and shoulder hurt. Wife took him to the ER at Hospital. He was transported to Hospital. 3/16/21 Hospital did a Heart catherization. He had a complete blockage in the widow maker and 2 stents were put in. He had 2 blood clots in the Widow Maker. 3/18/21 He was discharged from the hospital. He is doing ok but he has no energy.

COVID19 VACCINE	JANSSEN	1207655-1	50-59 years	2 days	Day 1 & 2 after shot - left arm hurt around injection site. Day 2 I felt very tired and some body aches. By Day 5 or 6 - full body aches and my arms felt like there was pressure on them. I was feeling very tired. As more days passed; I was feeling tired, could not raise my arms, legs were weak and hurting. If I did anything (shower or carry a simple laundry basket) my arms would hurt so bad, I was out of breath and my heart was pounding so hard. By the week of March 29th - I was laying down in the middle of the day, no energy at all. Called the doctor and because of the shortness of breath & Body aches, they would only schedule a video visit for Monday, April 5th. After talking to me, they schedule to see me that day at 11:45 AM. I had weak muscle response in my arms, pale, and out of breath. They did blood work. Two hours after getting home; they called and said I needed to get to the emergency room. My red blood cell count was dangerously low, and they ordered a blood transfusion. I sent 6 days in the hospital.
COVID19 VACCINE	JANSSEN	1207994-1	65+ years	2 days	Blood Clot on back of leg
COVID19 VACCINE	JANSSEN	1210630-1	50-59 years	2 days	Mother called health department today, 4/14/21, to report reactions son experienced after receiving vaccine 3/4/21. She stated that on 3/6/21 he started having headaches, weakness and leg cramps. He went to the hospital two times with complaints. On 3/15/21 he was unable to walk/drive because headaches were severe. On 3/30/21 he passed out, squad was called. He was not responsive and was put on a vent at the hospital. A ""scan"" showed blood clots in brain and heart. This individual passed away on 4/4/21.""
COVID19 VACCINE	JANSSEN	1210787-1	50-59 years	2 days	Pt developed abdominal pain and anorexia beginning two days after receiving vaccine dose. Presented to ED and found to have portal vein, SMV and splenic vein thrombosis. Underwent TIPS c/b recurrent thrombosis x 2 and cecal pneumatosis s/p exploratory laparotomy, open abdomen, delayed closure. He was mechanically ventilated and briefly requiring vasopressor support, now extubated and off pressors. Remains inpatient on anticoagulation and TPN. Hematology work-up while inpatient was negative.
COVID19 VACCINE	JANSSEN	1211097-1	50-59 years	2 days	Reported to local health department by physician office. Patient reported lower left leg swelling that started on 4/11/2021. Also, reported shortness of air. Venous doppler performed and positive for DVT on 4/12/2021. Patient admitted to hospital on 4/12/2021. Inpatient currently at facility. On Eliquis. Also, tested positive for COVID upon admission to hospital.
COVID19 VACCINE	JANSSEN	1214336-1	50-59 years	2 days	Patient had LLE swelling and pain, went to see PV provider the next day who recommended pt go to ER. Pt was diagnosed with nonocclusive SVT in the L short saphenous vein via ultrasound. Good prognosis, no CP or SOB.
COVID19 VACCINE	JANSSEN	1219249-1	40-49 years	2 days	2 days after receiving the vaccine I have been diagnosed with Deep vein thrombosis and pulmonary embolisms.
COVID19 VACCINE	JANSSEN	1225917-1	60-64 years	2 days	Bilateral pulmonary embolism. She had chest pain, SOB, tachycardia in 130s. . Presented to ED. CTA positive for bilateral PE with Left popliteal DVT. She was treated with systemic TPA and heparin. She is still hospitalized.
COVID19 VACCINE	JANSSEN	1229838-1	40-49 years	2 days	Left popliteal occlusive DVT confirmed on ultrasound
COVID19 VACCINE	JANSSEN	1232932-1	40-49 years	2 days	Two days after receiving vaccine, patient developed acute swelling and tenderness in right lower extremity and diffuse whole body urticaria.

COVID19 VACCINE	JANSSEN	1234080-1	30-39 years	2 days	4/10/21 Patient presented to Urgent Care with Arm Pain (left arm painful and tingly since COVID shot 4/8; now pain is different and there is a lump on her forearm she can feel). 4/13/21 Contacted the office to schedule an appointment regarding worsening symptoms. Scheduled appointment. 4/14/21 cont. Seen in office by PA for: 1. Left arm pain - tender nodule L forearm, will get US due to recent birth, Johnson and Johnson vaccine, FH of DVT, to r/o DVT causing the lump, await results. Symptomatic care in the interim, may use warm compresses. - USV VENOUS UPPER EXTREMITY DUPLEX LEFT; Future 2. Paresthesia of left arm - site of reported injection and superficial induration 1.5cm from acromion process, suspect SIRVA due to sit of administration of vaccine, recommend symptomatic care with warm compresses, gentle massage if benefit noted, pt is breastfeeding so recommend local care at this time, consider PT, pt declines at this time as she will be on vacation next week. Discussed possible cortisone injection but deferred due to recent COVID vaccine 6 days ago, pt agrees as there is some recommendation to avoid steroids in close proximity to vaccinations to avoid blunting the immune response 3. Family history of DVT - see #1 4/15/21 After speaking with the DVT clinic Dr contacted the patient and recommended she take an 81mg low dose daily aspirin, until symptoms resolve, around one month. And repeating venus duplex in 7-10 days. Determined she would go prior to her leaving for her trip as she planned to be out-of-town during that time frame. (Per provider result notes.) 4/16/21 Patient was seen in emergency department for: Patient presents for evaluation of multiple concerns. Following the Johnson & Johnson COVID-19 vaccine she was recently diagnosed with superficial thrombophlebitis in the left forearm by ultrasound, has been taking aspirin and symptoms have not worsened. Left upper extremity exam is quite reassuring today, I see no clinical evidence for DVT and she is neurovascular intact. I did not feel that repeat ultrasound was necessary at this time, but she does have this scheduled next week so I advised her to keep that appointment. She has a very slight headache which has been present since the day she received the vaccine, currently 2/10 without vision or other neurologic concerns. No abdominal pain. I have low clinical suspicion for CVST or PVT at this time. Advised return if she develops worsening headache or new neurologic symptoms. Patient complained of new onset left lower lateral breast pain and lump starting today. She is currently breastfeeding and notes decreased milk production today. She does have a tender fullness on exam but no redness or visible swelling, she is nontoxic and well-appearing without fever. She has history of mastitis in the past, but she states her PCP recommended she be evaluated for possible blood clot in the breast. Advised the patient that I have very little concern for that at this time, if anything it would be superficial and not amenable to anticoagulation but I did not feel that imaging was necessary at this time. I will cover her with antibiotics for lactational mastitis, she has cephalosporin allergy but states she had formal testing for penicillin allergy and tolerated this well so I prescribed Augmentin. She will use a warm compress and continue nursing, I did recommend she start on the right side to initiate let down on the left. 4/20/21 patient was seen in the office for: Patient presents for follow up of recent ED visit. She was seen here last week for left arm pain/nodule/paresthesia following her Johnson & Johnson vaccine. She also reported a slight headache that
COVID19 VACCINE	JANSSEN	1236650-1	50-59 years	2 days	I began having pain in my lower left leg later on Sunday (felt like a pulled muscle) but by Monday it was more painful. Since I had surgery (see above) my doctor sent me fir an ultrasound where a clot was found. Went to emergency room to further evaluate and get treated. Was given elequis and am taking for 3 months. Was told clot was likely related to immobility from injury, but wanted to report just for your consideration
COVID19 VACCINE	JANSSEN	1236887-1	65+ years	2 days	Extreme lower extremity swelling and pain. Evaluated in PCP office on 04/22/21, ultrasound of right LE was negative for blood clot. Patient's symptoms worsened and PCP referred patient to ER on 04/16/21 and CT of cheat revealed 3 clots in the lungs. Patient was admitted to hospital and stated on heprin therapy. Still currently inpatient awaiting approval to transfer for inpatient rehab due to decreased endurance and bilateral lower extremity pain which is affecting ability to ambulated without assistance.
COVID19 VACCINE	JANSSEN	1238678-1	18-29 years	2 days	Adverse event: Ischemic Colitis most likely from a blood clot Symptoms: stomach pain -> severe diarrhea -> diarrhea of only blood, no stool for 24 hrs Symptoms began Saturday after vaccination (which was administered Thursday afternoon) Treatment: hospitalization, steroids, antibiotics
COVID19 VACCINE	JANSSEN	1239726-1	30-39 years	2 days	Super sick 2-6 days after shot. Fever, chills, aches, headache, vomiting
COVID19 VACCINE	JANSSEN	1252411-1	60-64 years	2 days	I am hospitalized since Wednesday with blood clots in my lungs I have no underlying condition s
COVID19 VACCINE	JANSSEN	1256826-1	60-64 years	2 days	shortness of breath, foot swelling, chills, body aches, dry mouth, fatigue, wheezing, eye burning sensation, joint pain, Blood clots in lungs, prescribed Xarelto

COVID19 VACCINE	JANSSEN	1263423-1	40-49 years	2 days	New small left frontal venous infarct with evidence for cortical vein thrombus
COVID19 VACCINE	JANSSEN	1263467-1	50-59 years	2 days	Immediately after shot had fever and chills with flu symptoms for about 4-5 days after vaccination. On 3/22 went to urgent care for left elbow swelling which had never occurred before in this joint visit determined was olecranon bursitis. The very next day began complaining about leg pain around 3/23 and by 3/26/2021 pain was unbearable in the leg and went to ER where patient was then admitted for DVT and pulmonary embolisms.
COVID19 VACCINE	JANSSEN	1263472-1	65+ years	2 days	patient had a blood clot 2 days after receiving the J & J vaccine; she was hospitalized and released. We just learned of this when the patient was in to pick up a Rx—we are unsure if this was already recorded by the hospital that treated her—we were advised by our market manager to submit just in case they didn't submit at the hospital.
COVID19 VACCINE	JANSSEN	1263742-1	60-64 years	2 days	AE = PE/DVT. Difficult to say if vaccine played an ancillary role (very short time course). Treatment = anticoagulation with apixaban. Outcome = patient discharged from hospital in good condition after 2 days.
COVID19 VACCINE	JANSSEN	1263828-1	50-59 years	2 days	I was admitted to the ER on 4/12/21 with dizziness, lightheadedness, vertigo, some auditory issues, shortness of breath, swelling/puffiness of legs and feet, unusual coldness in extremities, and some minor pain in chest. CT-Scan revealed DVT in left leg and PEs in both lungs. Was given two shots of heparin over a 24-hour period and then Xarelto 15mg (oral) the following day.
COVID19 VACCINE	JANSSEN	1268669-1	40-49 years	2 days	Ended up with a blood clot in left leg, not a dvt clot.
COVID19 VACCINE	JANSSEN	1271574-1	65+ years	2 days	Flu like symptoms for 3 days, then continue loss of appetite, weakness, so much so that on April 5, 2021, I was taken to the emergency room for immediate treatment. The hospital then discovered 2 pulmonary embolisms (blood clots), one in each lung and pneumonia. At this time, I was extremely weak and in major physical stress. NOTE: I do not have a history of ever having blood clots.
COVID19 VACCINE	JANSSEN	1274581-1	30-39 years	2 days	Patient states he had no soreness to his left arm. Patient states he got a blood clot. He went to the doctor and his doctor told him that the blood clot he had was not related to the vaccine.
COVID19 VACCINE	JANSSEN	1283045-1	65+ years	2 days	On March 30th the patient had loss of appetite and headache. On March 31st the patient collapsed and was taken to the ER, the patient's oxygen was low. Patient's blood pressure had dropped and you could not wake him up all afternoon. The Ambulance took him to the hospital on April 1st where he had shortness of breath and blood clots in lungs. On April 1-2 the patient was leaking blood but the hospital staff could not find where so they gave him 3 units of blood. Patient also received 3 antibiotics for a rare pneumonia.
COVID19 VACCINE	JANSSEN	1289795-1	50-59 years	2 days	on 3/8/21 patient describes numbness which starts on left hip which goes down left leg. on 3/21/21 patient complains of 3 days of pain and swelling in left lower leg, calf, edema of the foot and ankle which is painful with movement. ultrasound negative. on 3/23/21 ultrasound shows Deep vein thrombosis is visualized in the left popliteal vein. progress note indicates no immobility or long car rides. No history of DVT or pulmonary embolus. Begin enoxaparin x5 days and then dabigatran.
COVID19 VACCINE	MODERNA	0954442-1	40-49 years	2 days	Developed chest tightness around right side of chest into back and SOB 50.5 hours after vaccination. Went to local ER and found to have a right lower lobe pulmonary embolism. Treated with Xarelto and sent home with outpatient follow up.
COVID19 VACCINE	MODERNA	0954804-1	40-49 years	2 days	Started with severe chills, body aches and feverish. The. Slight leg pain which worsened with time, swelling on the right leg calf, warm to touch and difficulty breathing. Got hospitalized on 1/16 21 with multiple clots in my right leg and clot in the lung. Still in the hospital now.
COVID19 VACCINE	MODERNA	0968026-1	30-39 years	2 days	Patient states he started having sudden onset of left facial droop, left-sided arm and leg 15 minutes prior to arrival on 1/23 while driving. Pt got the Moderna vaccine second dose 2 days ago (1/21). Patient denies any history of stroke, DVT, PE. tPA was administered. Found to have clot in the Right MCA territory and taken for mechanical thrombectomy to remove the clot. Patient remains hospitalized and further workup is going.
COVID19 VACCINE	MODERNA	0974346-1	65+ years	2 days	Received Moderna Covid Vaccine #1 on 12/26/20 in left arm. Had arm pain first few days. On 12/28/20 he began having right calf pain that worsened over the next few days. Was evaluated in Urgent Care and diagnosed with an extensive DVT. No history of previous DVT or venous issues. Pt was on Plavix and ASA at the time for dx of CAD.
COVID19 VACCINE	MODERNA	0975821-1	65+ years	2 days	Patient was admitted to hospital for Pulmonary Embolism

COVID19 VACCINE	MODERNA	0977238-1	65+ years	2 days	Vaccine admin Wed 3 pm. Thurs no problem. Friday am, patient woke up almost fully blind right eye.
COVID19 VACCINE	MODERNA	0977933-1	50-59 years	2 days	EventsPatient experienced segmental and subsegmental pulmonary emboli without other preceding no evidence for DVT, no history of inherited thrombophilia or previous pulmonary embolism, no underlying cancer, surgery, or stasis. The only other complicating factor would be that she has been taking estrogen therapy prescribed by gynecology which she discontinued the day prior to her vaccine.
COVID19 VACCINE	MODERNA	0995527-1	40-49 years	2 days	Thrombosis, right hepatic vein, Hepatic Abscess ( 10 cm)
COVID19 VACCINE	MODERNA	0998022-1	65+ years	2 days	Left deltoid IM injection on 1/26/21 Left upper extremity swelling on 1/28/21 Presented to clinic on 2/2/21 and was found to have an acute LUE DVT and an acute PE on CTA chest
COVID19 VACCINE	MODERNA	1024665-1	50-59 years	2 days	Developed severe pleuritic chest pain x 5 days, went to ER on 2/5/2021, D Dimer over 4000, CT chest showed bilateral segmental and sub segmental Pulmonary Emboli. Initial Ultrasound of legs was negative for DVT, follow-up U/S on 2/9/2021 was positive for large Femoral vein DVT. All family history, medical history and other risk factors for coagulation disorder was negative. I was initiated on anticoagulation therapy. (Enoxaparin)
COVID19 VACCINE	MODERNA	1026801-1	30-39 years	2 days	Central venous sinus thrombosis
COVID19 VACCINE	MODERNA	1028765-1	40-49 years	2 days	Bilateral PE with right heart strain and pulmonary infarct. COVID negative. Symptoms started 2 days after the vaccine progressively worsened. Diagnosed to day - 02/13/2021. Unknown whether this is an adverse event, but no history of coagulopathy or risk factors
COVID19 VACCINE	MODERNA	1036585-1	60-64 years	2 days	Patient called EMS approximately 1pm on 2/15 with complaints of generalized weakness. Upon arrival EMS found her to be diaphoretic and she had a witnessed syncopal episode with question of v-fib and seizures. She became unresponsive and had no pulse. CPR was begun and she was transported to ED. She remained asystole throughout. CPR was initially continued in the ED for approximately 30 minutes and then stopped with Time of Death noted at 13:27. ED notes noted ""suspect given history that patient experienced massive MI, PE or ruptured AAA"". Death certificate notes indicate ""significant conditions contributing to death after cardiac arrest; ASCVD"". ""
COVID19 VACCINE	MODERNA	1052229-1	65+ years	2 days	On Saturday 2/20 I had what appeared hemorrhaging through penis, it lasted 1/2 or so which looked like a menstrual cycle, there was a lot of blood loss, headache and I took blood thinner which helped. I called my doctor and they suggested if it didn't resolve itself I should go to urgent care.
COVID19 VACCINE	MODERNA	1069054-1	65+ years	2 days	Anxious; Tired; Blood clots in left leg, right leg and brain; A spontaneous report was received from a consumer who was also a 66-year-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and developed blood clots in the left leg, right leg, and brain, anxious and tired. The patient's medical history was not provided. Concomitant medications reported included vitamin D, magnesium, lisinopril, and vitamin B12. On 14 Jan 2021, approximately 3 days prior to the onset of symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number not provided) intramuscularly in the left deltoid for prophylaxis of COVID-19 infection. On 16 Jan 2021, the patient experienced immense pain in the middle of the night, and subsequently saw her primary physician. An ultrasound revealed blood clots in her left leg, right leg and brain. A hematologist and vascular surgeon were consulted. Patient was treated with apixaban while they are doing blood work. The patient also became tired and anxious. She noted that she never had comorbidities before and was upset that her life has completely changed. A repeat ultrasound was scheduled for 19 Feb 2021. The mRNA-1273 dose was discontinued in response to the event of blood clots in the left leg, right leg, and brain, anxious and tired. The outcome of events, blood clots in the left leg, right leg, and brain was considered unknown at the time of this report. The outcome of the events, tired and anxious were considered not resolved at the time of this report.; Reporter's Comments: Very limited information regarding the events has been provided at this time. Further information has been requested.
COVID19 VACCINE	MODERNA	1089038-1	65+ years	2 days	Patient died 2 days after COVID vaccination, concern for vaccine related death. Autopsy showed bilateral pulmonary emboli. No evidence death was vaccine related.
COVID19 VACCINE	MODERNA	1089057-1	65+ years	2 days	Acute Pulmonary Embolism, and Acute Deep Vein Thrombosis. He is active every day doing arm exercises and walking in place for exercise, and moving about his house with his walker, and this day was no different. He finished making breakfast and went to sit down on the couch, and had sudden-onset pleuritic chest pain. No other recent risks such as long car ride, illness, plane ride, or other immobility. Patient says the vaccine was Moderna second dose, given at pharmacy.

COVID19 VACCINE	MODERNA	1094949-1	65+ years	2 days	On March 5th I experienced shortness of breath around 1:30 that lasted for 10 minutes. I had no other symptoms and it subsided. On 3/9 around 2:30 am I had another episode of shortness of breath that lasted about 5 minutes. I was able to return to sleep. I went to work that morning and had shortness of breath, sweating, and dizziness. I drove myself to the ER where I was diagnosed with an acute saddle pulmonary embolism. I was admitted and started on IV heparin. On 3/10, I was also found to have a DVT in my right leg.
COVID19 VACCINE	MODERNA	1096879-1	40-49 years	2 days	sob, dx pulmonary embolism
COVID19 VACCINE	MODERNA	1104499-1	50-59 years	2 days	Developed numerous blood clots in left saphenous vein and likely pulmonary embolism (did not do test for embolism b/c I am allergic to the contrast but I was very short of breath for several weeks). Not sure if this is related to the vaccine since I was post bone surgery and also on estrogen therapy (ovaries removed 5 years ago) but I have not ever developed a problem before after surgery and while on estrogen.
COVID19 VACCINE	MODERNA	1105660-1	65+ years	2 days	Patient developed pulmonary embolisms 2 days after receiving the vaccination.
COVID19 VACCINE	MODERNA	1106403-1	50-59 years	2 days	Blood clots in the left leg, same side as the vaccine was given. Woke up approximately two days afterward (2/11/21) with muscle pain in the left thigh. The pain did not lessen over the week, assumed it was just muscle. The pain migrated down to my calf and then was too painful to stand on or walk on 2/18/21.
COVID19 VACCINE	MODERNA	1106505-1	65+ years	2 days	Ocular stroke. A black curtain dropped down over right eye. Went to ER on the 28th, and was admitted. Had a blood clot in the right eye. Carotid artery right side did not have stenosis, they do not know why she had a stroke. Doctor can't say that it was caused by the vaccine. She now has a permanent blind spot in right eye.
COVID19 VACCINE	MODERNA	1107356-1	65+ years	2 days	Blood clot in blood vessel in the left hand at the base of the middle finger causing darkening in the lower part of the finger and numbness in the whole finger.
COVID19 VACCINE	MODERNA	1108761-1	65+ years	2 days	bilateral pulmonary emboli
COVID19 VACCINE	MODERNA	1111688-1	65+ years	2 days	Pt. developed a deep vein thrombosis and subsequent pulmonary embolism after his 2nd moderna vaccination for covid 19. He developed symptoms about 2 days after his 2nd vaccination and was diagnosed about 2 wks later with L DVT and pulm embolism This pt. likely has a predisposition to clotting as he has a history of pulmonary embolism in 2015
COVID19 VACCINE	MODERNA	1117838-1	65+ years	2 days	Blood clot in lower right leg
COVID19 VACCINE	MODERNA	1118197-1	65+ years	2 days	2 days after receiving the second moderna vaccine my father experienced a stroke. He was transported to the emergency room medical center where he went thru a procedure to remove a clot in his left side brain. Prior to this vaccine my father was in good health and was very active and still works and owns and operates a restaurant. He has never had any problems like this before the vaccine. One day after the vaccine he was complaining about a pain on the left side of his neck area. He was doing paperwork at approx 7:40pm when he experienced the stroke. I had to call 911. My father is currently at the medical center recovering from the incident.
COVID19 VACCINE	MODERNA	1120117-1	65+ years	2 days	Blood clot in his lung
COVID19 VACCINE	MODERNA	1126609-1	60-64 years	2 days	CARDIOPULMONARY ARREST 2 DAYS AFTER RECEIVING SECOND MODERNA DOSE
COVID19 VACCINE	MODERNA	1135898-1	65+ years	2 days	Two days after vaccination on 3/3, deep, sharp pain in the upper right portion of the chest and the upper right back, to the point of painful inability to breath beyond shallow breaths. This pain subsided, but returned shortly after contracting and testing positive for Covid-19 on the 3/12, at which point i decided to go to the hospital emergency room, Well I was tested for and found to have a PE (pulmonary embolism ) in the upper right portion of my right lung.
COVID19 VACCINE	MODERNA	1139147-1	65+ years	2 days	I went into DKA, my left eye bled, my left arm has a blood clot I was in hospital 9 days and a rehabilitation place for 11 days.

COVID19 VACCINE	MODERNA	1142665-1	30-39 years	2 days	Working full time during this post injecting time but 2days later started with nausea and vomiting and then itching and then next day asthma started to flare up and by the next day it developed into full blown exacerbation. As everything worsened and couldn't control anymore with inhaler and even tried nebulizer, I went to hospital. I went to ER that day on 2/17. They did breathing treatments, several Blood tests, chest xrays, Epi injection, IV steroids and several other meds, oxygen, and was admitted. As it worsened I had to be intubated 3 different times, where I would get to point they thought could be weaned off and for a day or two and would be a little better and then would worsen again requiring me to be reintubated for a total of about 10 days on the ventilator. During this time on vent second time I developed pneumonia, staph/MRSA, UTI. After being put on vent 3rd time I had to be life flighted to bigger hospital ICU. Then after a few days they were able to wean of ventilator but during which time I developed laryngospasms. I continued to improve with breathing but mentioned I had leg pain and the said probably due to low sodium and lack of mobility. I was finally released on 3/5 and discharged home with home health but sent home in supplemental oxygen due to says dropping and poore tolerance without sitting O2 stay at hospital prior to DC home. After getting home the next day or two right leg pain worsened along with breathing worsening and HH sent me to PCP who discovered blood clots and sent me to local er, that day which was 3/8. That hospital evaluated breathing issues and took blood work and chest xrays, started me on heparin drip and sepsis protocol and then called in life flight to send me to bigger ICU hospital within a few hours after arrival which they debated on ventilator or bipap but ended up on bipap and flown to hospital. There I was treated for breathing issues, infection, clot, vocal cord dysfunction from the multiple intubations then sent home when stable again with home health RN, PT, PT and ST. Also during all this hospital stay I was treated 4x for covid and all negative. Then after coming home this last time on 3/13 i had 15-20lb with gain in a little over a week and in 3 of those last days almost 9lbs with abdominal distension and chest pain/ nausea/ dizziness/low BP but fluctuating high at times / high Hr, so referred back to PCP 3/23 who sent me to ER that day concerned of abd blessed, kidney and or liver issues/sepsis/etc. PCP sent to ER. They did blood work and Abd CT and xray not showing anything and blood levels of liver slightly elevated, with blood in urine and so they said nothing of concern even though I went from looking normal to 6/7 months pregnant in less than a week. Followed up with pulmonologist who said bases of lungs hypoventilated, PFT very poor, wheezing and tight and WBC still up and gave me more steroids and asthma meds. Went to urologist due to blood in urine and also having urinary retention. They advised me to self cath and I will follow up in 1 month to determine if they need to do more tests to look into it more. PCP still concerned about these new abd. And other symptoms, and referring to specialists (cardiologist, Gastroenterologist, and Nephrologist) along with others already seeing too find the root of what are causing these new problems and if other organs are being affected with this whole immune response. I work full time, had 3 kids and works out with no limitations in my daily activities or ability to function, however since all this and being the hospital for pretty much most of laar month, the ongoing breathing issues (which I'm still requiring O2 at home) and all the other medical issues and the
COVID19 VACCINE	MODERNA	1144403-1	65+ years	2 days	Fever (103.7) with rigors 1 PM Mar 16, 2021 Night sweats Mar 17, 2021 Left Foot tenderness and swelling Mar 18-19, 2021 Left calf swelling with pain Mar 19, 2021. 5 PM Left leg DVT diagnosis Mar 19, 2021. 8 PM (UltraSound) despite warfarin treatment with INR 3.1 measured Mar 19, 2021. at 8 PM Admitted Medical facility Mar 19, 2021 with fever noted in chart through Mar 21, 2021 Switched from Warfarin to Lovenox anti-coagulation therapy due to warfarin failure Mar 21, 2021 Released from hospital Mar 21, 2021 Seen in clinic by Nurse Mar 25, 2021 for follow up Phone visit Mar 24, 2021 Coagulation specialist
COVID19 VACCINE	MODERNA	1144446-1	65+ years	2 days	Received vaccine on 01/26/2021 and unknowingly experienced event. Early morning of 01/28/2021 had fainting spell and thought it was caused by low blood pressure. Felt fine for remainder of day. On evening of 01/29/2021 I started having strange symptoms. Could not concentrate, vision impaired and couldn't figure out what evening meds I needed to take. Decided to go? to hospital on 01/30/2021. Getting ready, I passed out and husband called emergency services. Husband learned later in the day that I had a stroke. Doctors i;nfo?rmed that had blood clots in heart and lungs. Doctors advi;se not to get second vaccine shot.

COVID19 VACCINE	MODERNA	1173969-1	50-59 years	2 days	Leg pain Shortness of breath , rapid heart rate , Dizziness , Nights sweat Symptoms started March 24 .Went to Urgent care April 2, they referred me to the ER . I went to the Hospital ER April 6 , They admitted me at noon after finding Blood Clot down my right Leg and Chest . 2 shots of Lovinox for 3 to for days
COVID19 VACCINE	MODERNA	1174144-1	65+ years	2 days	Pulmonary embolism, multiple, with no known cause, with symptom onset within 48 hrs of second Moderna vaccine administration. PE documented on chest CT 4/5/21
COVID19 VACCINE	MODERNA	1180842-1	50-59 years	2 days	Received 2nd Moderna Covid shot on 03/29/2021 and on 03/31/2021, felt what I thought was a muscle cramp that never went away. Went to urgent care where the shot was given on unspecified date and they diagnosed what I thought was a muscle cramp area, as a blood clot.
COVID19 VACCINE	MODERNA	1203834-1	18-29 years	2 days	Experienced multiple bilateral Pulmonary Embolism
COVID19 VACCINE	MODERNA	1205534-1	18-29 years	2 days	Pulmonary embolism- Shortness of breath, chest pain
COVID19 VACCINE	MODERNA	1205860-1	65+ years	2 days	Fatigue, dizziness, weakness. Issues with breathing caused hospitalization 3 days after shot. Blood clot located in lung and 2 in right leg. Hospital stay 11 days, step down facility roughly 2 weeks, PT/OT upon arrival home.
COVID19 VACCINE	MODERNA	1207844-1	65+ years	2 days	He got the vaccine, and didn't have any real reaction, anything unpleasant, he had a numb lip and 2 fingers were numb. He called his doctor and she told him to go to the ER, which he did at Hospital. They did a CAT scan of his brain. They tried to do an MRI and they pushed his head against the machine as his back is curved and he stopped breathing. They had given him 2 narcotics for anxiety before the scan. He was then transferred to Hospital in . He saw Cardiophysilogist/IM and he found that he had a blood clot (? where), and they inserted a pacemaker through his groin as his pulse dropped to 40 BPM. He was hospitalized for 7 days, and discharged him with instructions on what he is able to do. They started him on new blood pressure medicines for his kidney's. On 3/26/21, lot# 028A21A. He subsequently had the 2nd vaccine, and all liquids emptied from his body (vomiting and diarrhea), at the same time, and then he was fine once everything settled down which lasted for about 3-4 minutes and then he was fine.
COVID19 VACCINE	MODERNA	1209641-1	65+ years	2 days	patient was administered Moderna vaccine (initial shot) and within 48-72 hours became short of breath. He presented to my office for evaluation 4/14/2021 and found to have right leg DVT and massive bilateral pulmonary emboli with left lung infarction.
COVID19 VACCINE	MODERNA	1216090-1	65+ years	2 days	The patient received her Moderna Covid vaccine and a couple of days later she had shortness of breath and was brought to the hospital a couple of days later. They found multiple blood clots in her lungs. The hospital discharged her too early and she had to go back, They told her to get her second dose on her regular scheduled date.
COVID19 VACCINE	MODERNA	1219210-1	60-64 years	2 days	Clinic visit 4/7/21: ""60 y.o. year-old male who presents for left calf pain, swelling, and bruising that began on 03/27/2021. Patient states that 2 days prior to symptom onset he received the Moderna COVID-19 vaccine. He did have symptoms of fever 102 F for approximately 24 hours. After the resolution of his fever he notice swelling of the leg with tenderness any line of bruising going down the medial aspect of his leg. He noticed more prominence of varicose veins of the left leg and began using a compression stocking. His varicose veins seem to worsen with sitting as well as tenderness, and improves with walking. He notes a tenderness over the upper calf. He denies any history of DVT/PE. He notes that two brothers sustained blood clots, one he believes was in varicose veins which were ultimately stripped and the other he is not sure of the exact nature of the clots. He is unaware of any hereditary clotting disorder in his family. He denies any shortness of breath, difficulties breathing, or chest pains."" He was sent home with aspirin 325mg daily. Hospital admission 4/11/21 "" 60 year old male with no PMH comes in c/o LLE pain that originally started 2 weeks ago and intermittently getting worse. The pain started around the left calf and has moved its way up to his thigh/groin area. The pain is sharp, 7/10, worse when standing, slight improvement with aspirin. Pt denies tingling, numbness, CP, shob, N/V/D, blurry vision or weakness. Associated symptoms include erythematic rash around left inner thigh, tender to touch, and swelling of calf/thigh. He works with heavy machinery but is always sitting down 1-2 hours at a time. He does have family history of DVT/PE. He is not on any daily NSAIDs or other anticoagulation and denies smoking."" he was started on a heparin drip then transitioned to Eliquis and discharged the next day.""

COVID19 VACCINE	MODERNA	1219520-1	65+ years	2 days	3/26/21 Presents to ER with complaint of ""cough x3 weeks after choking on some coffee with progressive shortness of breath"" Wife reports O2 sat of 88% prior to coming to ER. HX of CAD, hyperlipidemia, COPD. Follows a pulmonologist. Scope was done after ""choking"" incident which was negative. Pulmonologist thought maybe he had Pulmonary Fibrosis. Patient never heard anything back. Cough and Shortness of breath got progressively worse and came to ER. Patient is positive for pulmonary emboli, was admitted to the hospital, and is receiving Eliquis.""
COVID19 VACCINE	MODERNA	1219778-1	60-64 years	2 days	38 hours after injection the patient experienced severe dizziness, vomiting. Couldn't walk. Moving slowly. Went to ER on Monday, and was diagnosed with Left Subclavian Thrombosis causing cerebellar infarction and requiring a subclavian thrombectomy.
COVID19 VACCINE	MODERNA	1235520-1	50-59 years	2 days	blood clots in the heart; had no energy, very weak, extremely weak; irregular heartbeats; couldn't walk very good; shortness of breath; coughing; chills; nausea; vomiting; This spontaneous case was reported by a consumer and describes the occurrence of INTRACARDIAC THROMBUS (blood clots in the heart), ASTHENIA (had no energy, very weak, extremely weak) and HEART RATE IRREGULAR (irregular heartbeats) in a 55-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Tumor and Arrhythmia. Concurrent medical conditions included Heart disease, unspecified in 2020. On 17-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 19-Mar-2021, the patient experienced DYSPNOEA (shortness of breath), COUGH (coughing), CHILLS (chills), NAUSEA (nausea) and VOMITING (vomiting). On 01-Apr-2021, the patient experienced ASTHENIA (had no energy, very weak, extremely weak) (seriousness criterion hospitalization) and GAIT DISTURBANCE (couldn't walk very good). On 09-Apr-2021, the patient experienced HEART RATE IRREGULAR (irregular heartbeats) (seriousness criterion hospitalization). On 12-Apr-2021, the patient experienced INTRACARDIAC THROMBUS (blood clots in the heart) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 05-Apr-2021 to sometime in April 2021 due to HEART RATE IRREGULAR, then from 05-Apr-2021 to sometime in April 2021 due to INTRACARDIAC THROMBUS, and then from 09-Apr-2021 to sometime in April 2021 due to ASTHENIA. On 25-Mar-2021, CHILLS (chills) and VOMITING (vomiting) had resolved. At the time of the report, INTRACARDIAC THROMBUS (blood clots in the heart), ASTHENIA (had no energy, very weak, extremely weak), HEART RATE IRREGULAR (irregular heartbeats), GAIT DISTURBANCE (couldn't walk very good), DYSPNOEA (shortness of breath), COUGH (coughing) and NAUSEA (nausea) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant medications were reported. Patient was placed on unknown medication to help dissolve blood clots for one or two months. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded

COVID19 VACCINE	MODERNA	1235627-1	50-59 years	2 days	<p>Could not walk; Leg was swollen; Nurse told him his leg was hot; blood clot in both his lungs; Blood clot in both his legs; Fast heartbeat; Soreness in left calf; Ultrasonography NOS abnormal; CT abnormal; Ankle and foot still swollen; This spontaneous case was reported by a patient and describes the occurrence of PAIN IN EXTREMITY (Soreness in left calf), GAIT DISTURBANCE (Could not walk), PERIPHERAL SWELLING (Leg was swollen), FEELING HOT (Nurse told him his leg was hot), PULMONARY EMBOLISM (blood clot in both his lungs), DEEP VEIN THROMBOSIS (Blood clot in both his legs), HEART RATE INCREASED (Fast heartbeat) and ULTRASOUND SCAN ABNORMAL (Ultrasonography NOS abnormal) in a 58-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 013a21a) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. Concomitant products included IRBESARTAN and LEVOTHYROXINE for an unknown indication. On 01-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 03-Mar-2021, the patient experienced PAIN IN EXTREMITY (Soreness in left calf) (seriousness criterion hospitalization). On 17-Mar-2021, the patient experienced GAIT DISTURBANCE (Could not walk) (seriousness criterion hospitalization), PERIPHERAL SWELLING (Leg was swollen) (seriousness criterion hospitalization), FEELING HOT (Nurse told him his leg was hot) (seriousness criterion hospitalization), PULMONARY EMBOLISM (blood clot in both his lungs) (seriousness criterion hospitalization), DEEP VEIN THROMBOSIS (Blood clot in both his legs) (seriousness criterion hospitalization) and HEART RATE INCREASED (Fast heartbeat) (seriousness criterion hospitalization). On 14-Apr-2021, the patient experienced JOINT SWELLING (Ankle and foot still swollen). On an unknown date, the patient experienced ULTRASOUND SCAN ABNORMAL (Ultrasonography NOS abnormal) (seriousness criterion hospitalization prolonged) and COMPUTERISED TOMOGRAPHY ABNORMAL (CT abnormal). The patient was hospitalized from 17-Mar-2021 to 20-Mar-2021 due to DEEP VEIN THROMBOSIS, PAIN IN EXTREMITY and PULMONARY EMBOLISM. At the time of the report, PAIN IN EXTREMITY (Soreness in left calf), GAIT DISTURBANCE (Could not walk), PERIPHERAL SWELLING (Leg was swollen), FEELING HOT (Nurse told him his leg was hot), PULMONARY EMBOLISM (blood clot in both his lungs), DEEP VEIN THROMBOSIS (Blood clot in both his legs), HEART RATE INCREASED (Fast heartbeat), ULTRASOUND SCAN ABNORMAL (Ultrasonography NOS abnormal), COMPUTERISED TOMOGRAPHY ABNORMAL (CT abnormal) and JOINT SWELLING (Ankle and foot still swollen) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Computerised tomogram: abnormal (abnormal) Abnormal. In 2021, Ultrasound scan: abnormal (abnormal) Abnormal. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown Route) was unknown. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Reporter did not allow further contact; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>
COVID19 VACCINE	MODERNA	1240236-1	50-59 years	2 days	Blood clot in mouth on day 2, 9, and 16 from first injection
COVID19 VACCINE	MODERNA	1285872-1	65+ years	2 days	<p>80 yo woman with hx of HTN, anxiety dneies any other conditions, presented to ER due to epigastric pain, vomiting x1. In Er presented with elevated heart rate, EKG with sinus tachycardia, regular rythm. CXR with COPD changes. There are bibasilar infiltrates suspicious for pneumonitis in the appropriate clinical setting. PATient admitted to unit for further treatment and workup. WBC 16.91 4/27/2021</p>

COVID19 VACCINE	MODERNA	1288125-1	50-59 years	2 days	Back pain have been severely bad after she took both doses; Arthritis have been severely bad after she took both doses; Drug Rash; Diagnosed with DVT; This spontaneous case was reported by a consumer and describes the occurrence of DEEP VEIN THROMBOSIS (Diagnosed with DVT) in a 50-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 11020A and 004M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Arthritis, Migraine and Back pain. Concomitant products included GALCANEZUMAB (EMGALITY [GALCANEZUMAB]) for Migraine. On 16-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 18-Jan-2021, the patient experienced DEEP VEIN THROMBOSIS (Diagnosed with DVT) (seriousness criterion medically significant). On an unknown date, the patient experienced BACK PAIN (Back pain have been severely bad after she took both doses), ARTHRITIS (Arthritis have been severely bad after she took both doses) and DRUG ERUPTION (Drug Rash). At the time of the report, DEEP VEIN THROMBOSIS (Diagnosed with DVT), BACK PAIN (Back pain have been severely bad after she took both doses), ARTHRITIS (Arthritis have been severely bad after she took both doses) and DRUG ERUPTION (Drug Rash) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. After getting the first shot on 16 Jan2021, she was diagnosed with DVT on 18 Jan 2021 and has been on blood thinner ever since then. She also takes Emgality, a migraine injection every month. She states that ever since she received the vaccine and has been put on blood thinner, she gets rash every month when she take Emgality injection. She also reported that her underlying conditions like back pain and arthritis have been severely bad after she took both doses of the vaccine. Patient is going to speak with her doctor first thing in the morning tomorrow. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1289866-1	60-64 years	2 days	On 4-15-21, patient started having breathing problems and shortness of breath. He had a cough that he had productive phlegm. He continued to get worse. On 4-18-21, he fell getting out of the shower and slumped onto the floor, stating that he couldn't breathe. His wife and neighbor took him to the local ER. His condition improved with oxygen. He was admitted on 4-18-21 and then was transported by Air Evac to ICU. He was placed on the ventilator prior to leaving on 4-21-21 and transferred to hospital. His condition continued to deteriorate and he passed away on 4-25-21.
COVID19 VACCINE	PFIZER\BIONTECH	0928339-1	Unknown	2 days	Developed a infrapopliteal DVT in the left leg two days after vaccine was received. I also had minor knee surgery on December 18, four days prior to receiving the vaccine. No risk factors/medical history for developing a DVT.
COVID19 VACCINE	PFIZER\BIONTECH	0959401-1	30-39 years	2 days	I was having episodes of dyspnea and non productive cough starting from 1/1/2021. On 1/13/2021 I experienced severe dyspnea and had loss of consciousness for 5 seconds and was found down. I was rushed to the hospital and diagnosed with multiple pulmonary embolus (about 9) which was treated with direct TPA via catheterization. I then recovered in the ICU and transitioned to oral anticoagulation and discharged home on 1/15/2021.
COVID19 VACCINE	PFIZER\BIONTECH	0965634-1	65+ years	2 days	1840 NSG staff notified that resident had fallen and was unable to get up. Upon arrival to resident, resident was lying on her right side outside of her room. Resident was severely diaphoretic and unable to state what had occurred. Resident had a blue tinge to her lips, wheezing bilaterally, equal strength bilaterally and very weak. BP 143/74, HR 66, O2 80%, temperature unable to read temporarily due to diaphoresis. respirations equal and labored at 22 breaths per minute. EMS called. RN and CNA staff stayed with resident while waiting for arrival of EMS. During this time, son called resident's phone and he was updated of the situation. Upon EMS arrival at 1700, resident was regaining orientation and was no longer diaphoretic. EMS bs was 143. O2 placed on resident by EMS with 12 lead to be done on transport. EMS left with resident at approximately 1907. SJH ED called and given report to RN. DON notified.
COVID19 VACCINE	PFIZER\BIONTECH	0972556-1	18-29 years	2 days	Having a head arch, chest pains and shortness of breath pulmonary embolism and was tested for COVID-19 and tested positive.

COVID19 VACCINE	PFIZER\BIONTECH	0974998-1	65+ years	2 days	patient presented to her primary care for evaluation of leg pain. Noted on US that patient had a DVT in Left distal superficial femoral and popliteal veins. patient was hospitalized for treatment as patient had recent diagnosis of GI bleed and would need close monitoring of blood thinning medications. Of note- patient is 1/3 hospitalized with cardiac/blood issues currently in this facility who received a vaccine from this pharmacy in the last month and all three patients have the same COVID vaccine lot number. Physician elected to have a VAERS put in on all patients to ensure investigation was properly handled.
COVID19 VACCINE	PFIZER\BIONTECH	0992985-1	65+ years	2 days	Sunday: tightness in chest Monday : short of breath with walking Tuesday: extreme shortness of breath Wednesday: continued worsening SOB- sent for labs/ chest xray Thursday: D-dimer back -4.53- sent to hospital CAT scan showed multiple pulmonary embolisms without cor pulmonale / ultrasound- multiple DVTs, hospitalized 01-21 to 01-23/ heparin drip, transitioned to apixiban Discharged home
COVID19 VACCINE	PFIZER\BIONTECH	1015867-1	65+ years	2 days	Left popliteal DVT
COVID19 VACCINE	PFIZER\BIONTECH	1017454-1	65+ years	2 days	Two days after receiving the vaccine, on Jan 28th, I noticed pain in my right lower back area. It went away so I didn't pay much attention to it. On Jan 29th, I woke up to stabbing pains in my right chest which continued to night of Jan 30th. Morning of Jan 31st, I was very short of breath and could hardly get around. I went to the ER in evening of Jan 31st. I was admitted due to two pulmonary embolisms in my lungs. Doctors were convinced I had Covid 19. However, three tests came up negative. I was put on a Heparin drip and then eventually on Eliquis. I have always been healthy up to this point and never had any clotting issues. I now am on Eliquis for at least six months (have to have a follow-on echocardiogram due to issues on right side of my heart.). I am convinced the vaccine triggered the clots.
COVID19 VACCINE	PFIZER\BIONTECH	1033349-1	65+ years	2 days	Pt initially had diffuse joint pain, then worsening pain and swelling in RLE. Had DVT u/s + for DVT No history of blood clots, no prior risk factors Cannot be certain that she did not have clot prior to vaccine, although she never had pain or swelling to this degree (1-2 mo prior thought skinny jeans were slightly tighter on R than L, but no visible swelling. Now with RLE 2x size LLE)
COVID19 VACCINE	PFIZER\BIONTECH	1035850-1	65+ years	2 days	Patient woke up on the morning of 2/6 with symptoms of a stroke. Rushed to hospital where clot found in brain. Recovered from initial stroke but then had another major stroke on 2/8 and never recovered.
COVID19 VACCINE	PFIZER\BIONTECH	1049931-1	65+ years	2 days	2 days after vaccination right thighs and right leg started to have pain similar to pain I got with polymyalgia rheumatica that I have had in past and I thought it was a flare up. A couple of days after that right leg started to swell and was warm. Went to ER on 1/29/2021 and had doppler which showed blood clots from groin area to below the knee. I was placed on Xarelto at that time. Got 2nd dose and about 24 hours latter back of thighs started to hurt again. Called doctor and applied heat and elevation and had no new swelling but I remain on Xarelto. Not sure if it was related but I have had no history of blood clots. 2 years previously broke my right patella and was with brace and no weight bearing for about 8 weeks and brace for 12 weeks without clot issues. Traveled by car a couple thousand miles last year and no issues.
COVID19 VACCINE	PFIZER\BIONTECH	1058741-1	65+ years	2 days	Patient developed extensive superficial thrombophlebitis of left leg within 36 hours of receiving the vaccine with no other provocative factor
COVID19 VACCINE	PFIZER\BIONTECH	1060991-1	65+ years	2 days	Blood clot in left leg, inside next to the knee
COVID19 VACCINE	PFIZER\BIONTECH	1071607-1	65+ years	2 days	Cellulitis left arm - red and swollen, 2 pulmonary embolism, right tibial blood clot
COVID19 VACCINE	PFIZER\BIONTECH	1074549-1	65+ years	2 days	Two days after receiving the vaccine the patient began experiencing shortness of breath. One week after onset of symptoms he presented to the hospital and was diagnosed with submassive pulmonary embolism. He underwent IR suction thrombectomy which removed 30% of the PE burden and spent two days in the ICU. He has now been transferred to the floor.
COVID19 VACCINE	PFIZER\BIONTECH	1092549-1	65+ years	2 days	blood clots dx'd via ultrasound on 2-20-21
COVID19 VACCINE	PFIZER\BIONTECH	1098455-1	18-29 years	2 days	vein thrombosis
COVID19 VACCINE	PFIZER\BIONTECH	1102472-1	30-39 years	2 days	Pulmonary embolism: vaccine shot 2 administered 3/8, symptoms (shortness of breath, rapid heart beat) began 3/10, diagnosed at medical center 3/12. (Also experienced typical "flu like" symptoms beginning 12 hours after vaccine and lasting ~48 hours.) Being treated with anticoagulants."

COVID19 VACCINE	PFIZER\BIONTECH	1104565-1	65+ years	2 days	BLOOD CLOT. Began feeling ill 2 days after 1st vaccine...headache, cold and tired. Developed pain in my abdomen area quite noticeable 4 days later. 6 days later had major pain, vomiting, bloody diarrhea. Went to ER morning of the 7th day....spent 4 days in hospital. Had a blood clot-Portal Vein Thrombosis. Put on Heparin drip in hospital...and Eliquis blood thinners after released. I have never been sick like that...never been on any prescription...always been healthy, walking 3-5 miles per day. My family feels that there must be a connection with the vaccine. One of my doctors said no...another said didn't think so, but unknown at this time.
COVID19 VACCINE	PFIZER\BIONTECH	1106369-1	65+ years	2 days	Pain for 4 or 5 days in left leg (that leg also has varicose veins), some swelling and tender to the touch. Fifth day became raised and warm to the touch, so went to Urgent Care Diagnosis: Occlusive and nonocclusive thrombus within a superficial vein underlying the region of concern
COVID19 VACCINE	PFIZER\BIONTECH	1108287-1	65+ years	2 days	Patient received 2nd dose on 3/1 and self-reported experiencing fever and lethargy for 3 days. Two days post dose, patient complained of her left leg hurting to her daughter. Daughter inspected leg and did not notice any swelling or warmth. Two days after that symptom started (4 days post dose), patient's leg felt better but she now had shortness of breath which she claims worsened for two weeks before presenting to the hospital where patient was diagnosed with a pulmonary embolism.
COVID19 VACCINE	PFIZER\BIONTECH	1112424-1	65+ years	2 days	DVT blood clot in leg
COVID19 VACCINE	PFIZER\BIONTECH	1112775-1	50-59 years	2 days	blood clot leading to brain stem stroke, intubation, shortness of breath and chest pain
COVID19 VACCINE	PFIZER\BIONTECH	1112779-1	65+ years	2 days	Just 38.5 hours after receiving my 2nd dose of the Pfizer Covid-19 Vaccine I suffered a Cerebral Vascular Accident, a CVA, a Stroke @ 5:05a.m. in our home. My entire right side was paralyzed & unable to speak. My husband alerted #911 & fortunately @ the hosp. I received immediate life saving care. I had a C.T. Scan which revealed #2 blood clots in the left side of my brain. Intravenous T.P.A. was administered & then a thrombectomy was performed. Hospitalized approx. 5:45a.m on Sun., Feb. 28th, 2021 till my discharge on Wed., March 3rd, 2021@ 5:30pm.
COVID19 VACCINE	PFIZER\BIONTECH	1114702-1	50-59 years	2 days	amaurosis fugax. Temporarily lost vision in top half of right eye - lasted about 15-20 seconds - blood clot in right eye. No past history of blood clots
COVID19 VACCINE	PFIZER\BIONTECH	1123265-1	65+ years	2 days	Patient presented to clinic on 2/28 with fluttering in chest. EKG showed potential atrial fibrillation. Patient subsequently admitted to hospital on 3/2 for new onset a fib and pulmonary embolism and VTE in right leg and was inpatient until 3/6/21.
COVID19 VACCINE	PFIZER\BIONTECH	1130052-1	40-49 years	2 days	She reports having a surgery on 1/4/2021. Received vaccine on 3/5/2021 and went to ED on 3/7/2021 and diagnosed with bilateral PE's.

COVID19 VACCINE	PFIZER\BIONTECH	1140696-1	65+ years	2 days	<p>Multifocal Intracerebral Hemorrhage; Disseminated Intravascular Coagulopathy; strokes, Ischemic and Hemorrhagic; strokes, Ischemic and Hemorrhagic; AML; Leukemia; Blood clot diagnosis; Sore lower leg; RDW Stand. Dev. H/RDW Coeff Var H; Platelet Count L, Platelet Vol L; Neutrophils L; Band Neutrophils H; Monocytes H; Metamyelocytes H; Myelocytes H; Absolute Neutrophils L; Other Cell Type Blast Like Cells H; This is a spontaneous report from a contactable consumer. A 70-year-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) lot number: EL9261, via an unspecified route of administration, administered in Arm Right on 02Feb2021 08:30 (Batch/Lot Number: EL9261) as SINGLE DOSE for covid-19 immunisation. Medical history included breast cancer (8 years ago no chemo just radiation). Historical vaccine included first dose of BNT162B2 (lot number: EL0140) on 11Jan2021 for Covid-19 immunization. Concomitant medication included vitamin c [ascorbic acid] (VITAMIN C [ASCORBIC ACID]), calcium citrate, colecalfiferol (CALCIUM CITRATE + D3), glucosamine, magnesium citrate, docosahexaenoic acid, eicosapentaenoic acid, tocopheryl acetate (OMEGA 3 [DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID;TOCOPHERYL ACETATE]) and curcuma longa (TURMERIC [CURCUMA LONGA]). On 04Feb2021, the patient's blood work result showed red cell distribution width (RDW) stand. dev. high; RDW coeff var high, platelet count low, platelet vol low; neutrophils low; band neutrophils high; monocytes high; metamyelocytes high; myelocytes high; absolute neutrophils low; other cell type blast like cells high. On 15Feb2021, the patient experienced sore lower leg. On 16Feb2021, the patient was diagnosed with blood clot. On 19Feb2021, the patient was diagnosed with leukemia. On 20Feb2021, the patient was diagnosed with acute myeloid leukemia (AML). On 21Feb2021, the patient had tow types of stroke, ischemic and hemorrhagic, the patient was intubated. On 23Feb2021, the patient was extubated and died due to multifocal intracerebral hemorrhage, disseminated intravascular coagulopathy, acute myeloid leukemia with blast crisis. The patient received chemotherapy and leukapheresis as treatment. The patient died on 23Feb2021. An autopsy was not performed.; Reported Cause(s) of Death: Disseminated Intravascular Coagulopathy; Acute Myeloid Leukemia With Blast Crisis; Multifocal Intracerebral Hemorrhage</p>
COVID19 VACCINE	PFIZER\BIONTECH	1150377-1	60-64 years	2 days	<p>Superficial blood clot on left calf at the lower end of some varicose veins two days after injection; Superficial blood clot on left calf at the lower end of some varicose veins two days after injection; This is a spontaneous report from a contactable consumer (patient). A 62-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot: EN6207), via an unspecified route of administration in right arm on 10Mar2021 14:30 (at the age of 62-years-old) as single dose for covid-19 immunisation. The vaccine facility type was a pharmacy or drug store. The patient had no other vaccine in four weeks. The patient did not have Covid prior vaccination and was not Covid tested post vaccination. Medical history included macular. Concomitant medication included amitriptyline. The patient previously took erythromycin and statins and experienced drug allergies from these. The reported adverse events were superficial blood clot on left calf at the lower end of some varicose veins two days after injection (on 12Mar2021 at 10:00). It may be unrelated, but the patient wanted to let know. The events resulted in emergency room/department or urgent care. AE treatment included hot compress, support stockings and ibuprofen (MOTRIN). The outcome of the events was recovering.; Sender's Comments: Varicose veins most probably was a preexisting condition, unrelated to BNT162B2 vaccine. The reported superficial blood clots are considered a complication of varicose vein and unlikely related to BNT162B2.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1152698-1	65+ years	2 days	stroke -venous thrombosis
COVID19 VACCINE	PFIZER\BIONTECH	1160323-1	65+ years	2 days	<p>My Ooxgyen was dipping into high 70s tolow 80s with oxygen @4 lpm, Also very dehydrated and went to hospital dur to feet and ankles swelling up alot.. In the hospital for 9 days to lower clots from legs and constant high oxygen therapy also hemoglobin and hematicrit went upper range. Im home now doing better, but I dont think I should take the 2nd dose.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1163438-1	50-59 years	2 days	After the first vaccine on 2/6/2021, I did not have any reaction except a sore arm until 2/10/2021 when developed a bad headache causing me to leave work. When I awoke on 2/11/21 I felt worse as the day went on until I had complete flu like symptoms. On Friday, 2/12, I went to my primary care doctor and they did a COVID-19 test which was negative. Hence, I just waited for the reaction to go away, I was not better and able to resume normal activity until 2/15/21. I did decide to get the second shot as I was not entirely sure it was a result of the vaccine. On 2/27/2021, I received the second vaccination. Again, the immediate side effect was only a sore arm. On the following Monday (3/1/2021) see cont.I began to have what I thought was muscle aches and pains around the mid section on my body but they were manageable. On Tuesday and Wednesday (3/3/2021) the pain and area of the pain spread and intensified. I was unable to sleep or find a comfortable position and was losing strength and knew I needed medical attention as I was afraid it was a heart issue. My husband took me to the ER (3/4/2021). The ER doctor ran a CT scan with contrast and the result was a blood clot in my right lung and pneumonia in my left lung along with pleurisy. I was then admitted to Clinic on 3/4/2021. I remained in the hospital until 3/7/2021. There I was treated with IV antibiotics, warfarin, Lovenox (80mg), and pain medication for the pleurisy. I was also on a full time heart monitor and my heart was checked several times. Since returning home, I finished a dose of two antibiotics and am using an inhaler to help with breathing. I have also just finished a long dose of steroids. My INR is still not regulated to the therapeutic level. Prior to this reaction, I was in the therapeutic range and had been checked. As of 4/3/2021 I am at 1.8 not in the 2-3 range and have increased my dose from before the reaction at 7.5 mg to 9.0 mg daily.
COVID19 VACCINE	PFIZER\BIONTECH	1171204-1	60-64 years	2 days	Patient fell while on the job on Friday March 26th, slurred talking. Later slumped over in the car while driving and had to be taken to the Emergency room where he later passed away. Cause of death on the death certificate per the coroner is Pulmonary Embolus. Patient was just seen by his family physician in January and was in good health no medications taken other than eye drops.
COVID19 VACCINE	PFIZER\BIONTECH	1175716-1	65+ years	2 days	1st symptom 3/19/21 at 5:30 am - Weakness in fingers on right hand. Called nurse line, they recommended calling EMT. EMT said no stroke but could go to urgent care for further evaluation. Urgent care recommended ER. ER recommended appointment with Neurology 2nd symptom 3/21/21 slight droop on right side of mouth. Went to ER in Hospital. MRI revealed clot. Additional ultra sound of heart and carotid arteries clear. Final diagnosis: Subacute CVA-Lt Centrum Semiovale w/ right facial droop and right hand deficits. Recommendations: Neurology evaluation, Outpatient PT/OT for right hand deficits. Hospitalization: 1 day Hospital Name: Unnamed City: Unnamed State: Unnamed
COVID19 VACCINE	PFIZER\BIONTECH	1178410-1	50-59 years	2 days	I began developing pain in my left leg Friday, March 19th - two days after receiving my second injection. My early Monday morning I was in so much pain that I went to the ER. I was diagnosed with acute DVT in my entire left leg from the Iliac vein in my abdomen down to the ankle. The entire leg was occluded.
COVID19 VACCINE	PFIZER\BIONTECH	1183938-1	30-39 years	2 days	I began to bleed and pass blood clots from my vagina; I began to bleed and pass blood clots from my vagina; This is a spontaneous report from a contactable consumer (patient). A 32-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in the left arm on 11Mar2021 01:15 (at the age of 32 years) (Batch/Lot Number: EN6208) as a single dose for COVID-19 immunisation. Medical history included birth control. Concomitant medications were not reported. The patient is not pregnant. On 13Mar2021 04:00, the patient began to bleed and pass blood clots from her vagina. The event blood clots was assessed as serious (medically significant). The patient visited the doctor for the events and the events were given treatment. The outcome of the events was not recovered.
COVID19 VACCINE	PFIZER\BIONTECH	1184334-1	65+ years	2 days	Two days after vaccine experienced shortness of breath and tachycardia. Went to ER. After testing, diagnosed with pulmonary emboli in each lung (one each). 1 blood clot also found in ankle.
COVID19 VACCINE	PFIZER\BIONTECH	1194772-1	65+ years	2 days	less than 2 days after second Pfizer vaccine near syncope, hypoxic and DEVELOPED SUBMASSIVE PULMONARY EMBOLISM. NO OTHER KNOWN RISK FACTORS OR ACUTE EVENTS FOR CAUSE OF Pulmonary embolism and no prior dvt/pe
COVID19 VACCINE	PFIZER\BIONTECH	1194958-1	60-64 years	2 days	2 days after I received the vaccine had difficulty breathing shortness of breath and on 5 and 6 days also then had chills hand tremors loss of appetite nausea this continued for 2 more months. I went to Urgent care and on March 26 then found a clot in my right lung. I am on warfin now and none of these symptoms did I have prior to the vaccine. I had 5 covid tests to see if I had COVID but all the tests were negative.

COVID19 VACCINE	PFIZER\BIONTECH	1202588-1	50-59 years	2 days	Adverse event #1: Flu-like symptoms, severe headache, vision blurriness, lasting roughly 10 days. Adverse event #2: Deep Vein Thrombosis in the left Popliteal vein with moderate associated edema and pain. Required Emergency Room visit, diagnosis, and treatment with Eliquis. This event prevented normal daily work activities for 5 days, after which edema and pain has mostly subsided.
COVID19 VACCINE	PFIZER\BIONTECH	1203491-1	50-59 years	2 days	Pt reported to the ER two days after vaccination on 03/12/21 with complaints of visual difficulties and gaze abnormalities. Stroke code was activated at 1445. After CT, pt was flown to Hospital for work up by neurology. Underwent CTA, thrombus in right PCA. Underwent thrombectomy. Complications from stroke and difficult airway led to intubation and mechanical intervention, extubated the next day. Pt discharged from hospital 03/17 on Eliquis.
COVID19 VACCINE	PFIZER\BIONTECH	1204448-1	50-59 years	2 days	To summarize our conversation, you stated that you received the second Pfizer vaccine on 3/4/21. Three days later, on 3/7/21, you began to have fatigue, shortness of breath, dizziness and chest pressure. Because all symptoms continued for 24 hours, on the evening of 3/8/21, you took yourself to the Emergency Department. Your ER work-up included a CXR (negative), an EKG (showing a left bundle branch block), serum bloodwork (negative for MI), however, the D-dimer and spiral CT were both positive for a pulmonary emboli (i.e. a blood clot in your lungs). You were admitted to the hospital and started on the blood thinner, Eliquis. During your 3-day hospital stay, your work-up also included a bilateral lower extremity Doppler study (negative) and an echocardiogram (showing left ventricular hypertrophy). You were discharged on all of your previously prescribed medications (see list below), except for the fish oil. You were also started on Eliquis. Since discharge, you have followed up with your PCP and have been referred to a cardiologist and pulmonologist. To date, you have had no further symptoms. PAST MEDICAL HISTORY: hypertension, hypercholesterolemia, pre-diabetes. PRE-VACCINE MEDICATIONS: losartan, HCTZ, amlodipine, Welchol, fenofibrate, fish oil. POST-ER VISIT MEDICATIONS: losartan, HCTZ, amlodipine, Welchol, fenofibrate, Eliquis.
COVID19 VACCINE	PFIZER\BIONTECH	1211441-1	50-59 years	2 days	fatigue mild headache shortness of breath chills low grade fever diagnosed with ACUTE PULMONARY EMBOLISM WITHOUT ACUTE COR PULMONATE had two hospital doctors two hematologist two pa-c specialist all suspect pfizer shot . taking eloquis for 90 days
COVID19 VACCINE	PFIZER\BIONTECH	1219720-1	50-59 years	2 days	patient received vaccine on 4/7 and developed N/V on 4/9. Presented to hospital on 4/15 with portal vein thrombosis.
COVID19 VACCINE	PFIZER\BIONTECH	1224262-1	18-29 years	2 days	strange pain on her left collar bone; going to see someone just in case it's a blood clot; lump on her collar bone, left collar bone; does hurt a little bit; This is a spontaneous report from a contactable consumer or other non hcp (patient herself). A 19-years-old female patient received bnt162b2 (BNT162B2, Formulation: Solution for injection), dose 1 intramuscularly administered in Arm Left (like the shoulder area) on 28Mar2021 09:00 (Lot Number: ER8734 and Expiry date: unknown) as single dose for covid-19 immunisation. The patient medical history was not reported. There were no concomitant medications. No additional Vaccines administered on same date of the Pfizer suspect. On 30Mar2021, the patient experienced going to see someone just in case it's a blood clot, lump on her collar bone, left collar bone, does hurt a little bit and on unspecified date strange pain on her left collar bone. 19-year-old female got the first Pfizer Covid vaccine at 9 am on Sunday, March 28 and this morning, she woke up with a strange pain on her left collar bone and there was a lump there, states when she woke up, she noticed a pain, checked in the mirror, she saw on the left side she saw a bump and checked on the right side and didn't see anything and that's when she got worried. Caller states she was just calling to report it, she's worried that it's a blood clot or something else. Why was the patient taking Pfizer BioNTech COVID Vaccine (Verbatim): she wanted to be vaccinated to protect herself and her community. Caller states she would not like to provide her last name at this time. However, provided her last name initial. She also reports she would not like to provide her address, height, or weight right now. She states she used to volunteer at a hospital. She does not see expiration or NDC number on card she received when she got her vaccine. Caller states she does know that one of her family members has the Factor 5. She is not sure if she has it but would like to be tested for it. The outcome of the event going to see someone just in case it's a blood clot was recovered, lump on her collar bone, left collar bone and does hurt a little bit was not recovered and strange pain on her left collar bone was unknown. Information on batch/Lot number has been requested.

COVID19 VACCINE	PFIZER\BIONTECH	1224436-1	65+ years	2 days	<p>deep vein thrombosis on Sunday; Extreme fatigue on Friday; This is a spontaneous report received from a contactable consumer. A 72-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6208) via unspecified route on left arm single dose for COVID-19 immunization on 17Mar2021, 10:45 AM, at 72-year-old. Medical history was not reported. The patient had not had COVID prior vaccination. Concomitant medications in two weeks included: fluoxetine 20 mg; atorvastatin 10 mg. The patient had not had other vaccine in four weeks. The patient previously took morniflumate (FLOMAX) and had allergy to it. The patient was extreme fatigue on Friday 19Mar2021 and deep vein thrombosis on Sunday 21Mar2021 06:00 PM. I was hospitalized for two days including a veinogram to remove the blood clots from my left leg. I'm now taking rivaroxaban (XARELTO) 15 mg twice a day and were wearing a compression sock for my left leg. Treatment also received as IV heparin. Emergency room/department or urgent care involved and reported as serious due to hospitalization for 2 days. The patient had not had COVID tested post vaccination. Outcome of the events was resolving.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1227968-1	30-39 years	2 days	<p>DVT (Phlegm Asia Cerulean Dolmens); This is a spontaneous report from a contactable health care professional (patient). This 30-year-old female patient (not pregnant) received 2nd dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EL9262) at single dose via an unknown route in left arm on 27Jan2021 12:00 PM for Covid-19 immunization. Medical history included urinary tract infection. Family history included chronic kidney disease (CKD). No other vaccine in four weeks. No Covid prior vaccination. Other medications in two weeks included spironolactone 50 mg, daily. Historical vaccine included 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EL3248) at single dose via an unknown route in left arm on 06Jan2021 17:30 for Covid-19 immunization. The patient experienced DVT (Phlegm Asia Cerulean Dolans) on 29Jan2021 05:00 AM. AE resulted in Emergency room/department or urgent care, and was serious due to hospitalization and life threatening illness (immediate risk of death from the event). The event resulted in 2-day hospitalization. Known allergies included and had reaction (hives) to apixaban (ELIQUIS) upon discharge from hospital after thrombectomy. Covid tested (saliva) post vaccination on 13Feb2021 was negative. The event treatment included thrombolysis, thrombectomy. Outcome of the event was resolved with sequel (reported as recovered with lasting effects).; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported event deep vein thrombosis occurred in a plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Committees and Investigators, as appropriate.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1227974-1	50-59 years	2 days	DVT in right leg; chest pain; PE in right lung was found on CT scan; numbness in both legs; Back pain; This is a spontaneous report from a contactable consumer (patient). A 50-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) dose 1 via an unspecified route of administration, administered in arm left on 18Mar2021 13:30 (Lot Number: EP7534) as single dose for covid-19 immunisation. Medical history included breast cancer, hypothyroidism, diabetes. The patient did not have covid prior vaccination and no covid tested post vaccination. No known allergies. The patient was not pregnant. Concomitant medications in two weeks included metformin; atorvastatin (LIPITOR); levothyroxine sodium (SYNTHROID), vit d, multivitamin. No other vaccine in four weeks. Back pain started on 20Mar2021, chest and back pain on 24Mar2021 and chest pain continued until she went to the ER on 27Mar2021. When PE in right lung was found on CT scan on 23Mar2021 12:00 PM. The patient was hospitalized on 27Mar2021 and heparin was started and continued until 29Mar2021 when she was released. The DVT in right leg was found on 28Mar2021 with ultrasound after she mentioned numbness in both legs on 23Mar2021 12:00 PM. She started apixaban (ELIQUIS) on 29Mar2021 before leaving the hospital and still taking it now. She went to follow up appointment with hematologist that suggested that she remained on apixaban and return in 10 weeks for another checkup. The events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event). Number of days hospitalisation was 3. Treatment received for events included heparin and apixaban. The outcome of events was recovering. The patient received second dose of BNT162B2 in arm left on 09Apr2021 12:30 (Lot Number: EK8727).
COVID19 VACCINE	PFIZER\BIONTECH	1227977-1	Unknown	2 days	Pulmonary embolism/ blood clot/ passed out; This is a spontaneous report from a contactable consumer (patient's daughter). A male patient of an unspecified age received BNT162B2 (Pfizer COVID-19 vaccine), dose 1 via an unspecified route of administration, administered in arm, side unknown, on 24Mar2021 14:30 (Lot Number: EN6208) as single dose for COVID-19 immunisation. Vaccination facility type was clinic. Medical history included colon cancer in 2011. He had cancer in 2011 but resolved that year without chemotherapy or radiation. His lab work was good. There were no concomitant medications. No prior vaccinations (within 4 weeks). No family medical history relevant to AE. The patient experienced pulmonary embolism on 26Mar2021 with fatal outcome. The reporter was reporting on the Pfizer COVID vaccine that her father received. She stated he died from a blood clot after receiving the first dose. Stated she needs help because he had no health issues and he died. She just wanted this information to be out there and for people to be aware. This morning they had been reading on the news that the Johnson and Johnson vaccine is on hold. It seems to be put on the market without research. She felt like her father was a guinea pig. Her mother didn't want to get her second dose. Stated there seems to be an issue with Pfizer too. Her father had no issues whatsoever. His death certificate stated the cause of death was a pulmonary embolism, but he had no history of blood clots. Passed away Friday 26Mar2021 at 11:33 am. The reporter stated when he went to Emergency Room they thought he was having a heart attack. All physicians were wondering what happened because he had no health issues. The event required a visit to the emergency room that day because he passed out at his job. The patient underwent lab tests and procedures which included lab work: good in 2011. The patient died on 26Mar2021. An autopsy was performed that revealed pulmonary embolism.; Reported Cause(s) of Death: Pulmonary embolism; Autopsy-determined Cause(s) of Death: Pulmonary embolism
COVID19 VACCINE	PFIZER\BIONTECH	1240013-1	65+ years	2 days	not feeling well and short of breath on 2/11/21, 2/12/21 more short of breath ambulance came. Went into PEA in ambulance with CPR. They gave TPA for suspected blood clot. He initially improved. He did not recover and died 4/4/21. He spent the entire time in hospital or TCU with complications. We brought him home 4/2 to die at home.

COVID19 VACCINE	PFIZER\BIONTECH	1255643-1	30-39 years	2 days	<p>Looked like he was in sepsis; thrombus occluding his IMV protruding into part of the SMV; Thrombocytopenia; Bacteremia with E. Coli; Unable to tolerate diet; Abdominal pain; Nausea; Vomiting; Muscle aches; Chills; Fever; This is a spontaneous report from a contactable physician. A 36-year-old male patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration, on 06Apr2021 at 10:00, at the age of 36 years old, for COVID-19 immunization. The patient's medical history included diverticulitis ongoing since 05Nov2018. Concomitant drugs included escitalopram oxalate (LEXAPRO) ongoing since an unspecified date. There were no other vaccinations 4 weeks prior to receiving BNT162b2. Two days after vaccination, on 08Apr2021, the patient developed nausea, vomiting, muscle aches, chills, and fever. The patient continued to have these symptoms and then developed abdominal pain on 11Apr2021, so the patient went to ER. Nausea, vomiting, muscle aches, chills, fever, and abdominal pain were reported as medically significant events. A CT of the abdomen and pelvis was performed on 11Apr2021, which seemed at that time to reveal only uncomplicated diverticulitis. Therefore, the patient was sent home with oral antibiotics. Then, the patient presented back to ER on 14Apr2021: the patient couldn't tolerate his diet and was experiencing worsening of abdominal pain. Another CT of abdomen and pelvis was therefore done on 14Apr2021, which this time revealed a thrombus occluding his IMV protruding into part of the SMV and the portal vein. In light of this finding, on 14Apr2021 the medical staff retroactively looked at the patient's CT scan from 11Apr2021 and they found that the thrombus was already present but less evident than on 14Apr2021. The patient also looked like he was in sepsis, so the medical team was performing a full septic work-up and the patient was hospitalized on 14Apr2021. The patient was terrified, and the medical staff were ruling out acute mesenteric ischemia. On 14Apr2021, blood work showed thrombocytopenia, and a bacteria blood test showed bacteremia with E. Coli. The event thrombus was reported as serious since medically significant, life threatening, and requiring hospitalization. No information regarding seriousness was provided for thrombocytopenia and bacteremia. Treatment with heparin drip was started (ongoing at the time of the reporting) and the patient improved. However, the reporter stated that at the time of the last reporting, all of the patient's symptoms were ongoing, that all of the patient's symptoms had worsened. At the time of the last reporting the patient was in the ICU. The patient had not recovered from the all reported events. The reporter did not know if the reported events were related to BNT162b2, however she added that diverticulitis could also cause all the patient's side effects. Information on the lot/ batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the thrombosis, sepsis and other reported events due to temporal relationship. However, the reported events may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including MRI of abdomen and vascular angiogram, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report</p>
COVID19 VACCINE	PFIZER\BIONTECH	1261830-1	40-49 years	2 days	<p>Blood clot in leg; This is a spontaneous report from a non-contactable consumer reported for himself. A 42-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via unspecified route of administration on 01Apr2021 02:00 PM at 42-year-old at single dose for COVID-19 immunisation. Patient had known allergies (unspecified) and other medical history (unspecified). There was no covid prior vaccination. There is no other vaccine in four weeks. Other medications in two weeks included antibiotics. Patient experienced adverse event: blood clot in leg on 03Apr2021 02:00 AM. The adverse event resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Life threatening illness (immediate risk of death from the event). Patient received treatment for events included blood thinners. Patient had covid tested post vaccination on 21Apr2021: Nasal Swab: Negative. Patient was not recovered. No follow-up attempts are possible; information about lot/batch number cannot be obtained.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1266039-1	65+ years	2 days	big heart blood clot; This is a spontaneous report from a contactable consumer. A 66-year-old male patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Left on 21Mar2021 12:00 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation (Age at vaccination: 66 years). Medical history was reported as none. There were no concomitant medications. The patient experienced big heart blood clot on 23Mar2021 14:00. Therapeutic measures were taken as a result of big heart blood clot. Outcome of the event was not recovered. No follow-up attempts are possible; information about lot/batch number cannot be obtained.
COVID19 VACCINE	PFIZER\BIONTECH	1269690-1	40-49 years	2 days	pulmonary embolism; pain on my stomach upper right side; difficulty breathing; This is a spontaneous report from a contactable consumer (patient). A 46-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: EW0150), via an unspecified route of administration, administered in arm left on 05Apr2021 16:00 (at the age of 46-years-old) as a single dose for COVID-19 immunisation. Medical history was not reported. Concomitant medication included spironolactone taken for an unspecified indication, start and stop date were not reported. On Wednesday, 07Apr2021, the patient started experiencing pain on her stomach upper right side and had difficulty breathing. Thursday, 08Apr2021 the symptoms worsened so Friday morning, 09Apr2021, she went to Urgent Care and they sent her to the hospital ER. Friday evening, 09Apr2021 she has been admitted to the hospital with pulmonary embolism. She was released from the hospital on Sunday, 11Apr2021. Currently taking warfarin and enoxaparin injections. The patient underwent lab tests and procedures which included SARS-COV-2 test: negative on 09Apr2021. Therapeutic measures were taken as a result of all events. The outcome of the events was recovering.
COVID19 VACCINE	PFIZER\BIONTECH	1269706-1	40-49 years	2 days	DVT behind left knee detected at ER on 08Apr. Pain behind left knee started on 4Apr; This is a spontaneous report from a contactable consumer (patient himself). A 47-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 2 via an unspecified route of administration, administered in the left arm on 02Apr2021 at 12:00 (Batch/Lot Number: ER8734) as a single dose for COVID-19 immunization. Relevant medical history included prior deep vein thrombosis (DVT) behind right knee from an unspecified date in 2010 to an unknown date. Concomitant medication included finasteride (PROPECIA) taken for an unspecified indication, start and stop date were not reported. The patient previously took ibuprofen (ADVIL), acetylsalicylic acid (ASPIRIN), and unspecified salicylates, from which the patient had known allergies. The patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) on 12Mar2021 at 12:00 PM (lot number: EN6204) at the age of 47 years, administered in the left arm for COVID-19 immunization. The patient had no other vaccine in four weeks. The patient had no COVID-19 prior vaccination. The patient was not tested for COVID-19 post vaccination. The patient had DVT behind left knee detected at the emergency room (ER) on 08Apr2021; the pain behind left knee started on 04Apr2021. The adverse event (AE) resulted in an emergency room/department or urgent care. Therapeutic measures were taken as a result of the event, which included that the patient was prescribed apixaban (ELIQUIS). The patient was not recovered from the event.

COVID19 VACCINE	PFIZER\BIONTECH	1269769-1	30-39 years	2 days	<p>Blood clots; Major blood loss; Blurred vision; Heart palpitations; Shortness of breath; Extreme fatigue; Dizziness; This is a spontaneous report from a contactable other hcp (patient). This 37-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in arm left on 29Mar2021 12:00 (Lot number was not reported) as single dose (at 37 years old) for COVID-19 immunisation. Medical history none. There were no concomitant medications. On 31Mar2021 01:00, the patient experienced blood clots, major blood loss, blurred vision, heart palpitations, shortness of breath, extreme fatigue, dizziness. The outcome of the events was unknown. Therapeutic measures were taken as a result of the events included blood transfusion, ongoing tests, ultrasounds. The events required a visit to the emergency room and a visit to the physician's office. Seriousness criteria of the events was reported as serious due to disability and life threatening. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19. No allergies. The patient was not pregnant at the time of vaccination. The information on the Lot / Batch number has been requested.; Sender's Comments: Based on the limited information currently available, a possible association of the suspect drug administration with the reported events cannot be completely excluded, due to a plausible temporal relationship. This case will be reassessed when additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1270988-1	65+ years	2 days	<p>After 2nd Vaccine on 3/6/21, she became ill on 3/8/21, fever and chills was in bed all day on 3/9/21 with the same symptoms. Woke up on 3/9/21 with shingles, Her PCP was treating her with Famciclovir and Gabapentin for pain. She no longer had the fever or chills but still didn't feel well. On 3/17/21 she was admitted at Medical Center which she was treated for a blood clot in her lung and for pericardial effusion. She was put on blood thinners which then caused a bleed in her hip bone. She had a surgery to put a filter in to stop more blood clots and to drain the fluid from her heart. She died on 3/27/21 around 3:30pm.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1278730-1	50-59 years	2 days	big bump on arm; rash/red blotch on arm; nose bleed, blood clots coming out of nose; nose bleed, blood clots coming out of nose; This is a spontaneous report from a contactable consumer (patient). A 52-year-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular, administered in the left arm on 05Apr2021 (Batch/Lot Number: EW0151) as single dose, for covid-19 immunization. Medical history included ongoing sjogren's syndrome and ongoing lupus. Concomitant medications included levothyroxine sodium (SYNTHROID) taken for an unspecified indication, start and stop date were not reported. 07Apr2021, she started having a nose bleed. She explains she wasn't doing anything in particular, just talking on the phone, and blood just started pouring out of her nose. Blood clots started coming out as well. She ended up calling 911 and they sent an ambulance. The EMS helped her stop the bleeding. She didn't go to the ER or anything. However, she is getting implants done for her upper teeth so she wanted to double check and make sure nothing was pressing against her nasal cavity because the nose bleeds were so off/random. The doctor said there was no pushing. The doctor completed a panoramic exam/x-ray and confirmed there was nothing pushing. The doctor did suggest she go to the ENT. She made an appointment with an ENT doctor for the following day, 08Apr2021, and the ENT put a camera down. She confirms she explained to them she just had the vaccine and she was googling information. She was told to not google anything and to let them check it out. The caller states she explained to the ENT the reason she was there was because she was concerned, she is not a nose bleeder and nose bleeds never happened to her. Once blood clots started coming out that way, she was terrified. They didn't see anything alarming, but they wanted to make sure and do further research, so basically they planned to do a CT/CAT scan. She was scheduled for a CT/CAT scan on Monday, 12Apr2021, but she was allergic to the contrast and was sent home because they were not prepared for pre-medication. She is waiting for the doctor to schedule another appointment so she can go back. She felt she needed to report these nose bleeds because she has been seeing Johnson & Johnson had severe blood clots, but she took Pfizer's vaccine, and was also getting blood clots. Her nose bleeds just happened right after both vaccines. On an unspecified date, she had a little bump that went away. She had this big bump on her arm and a big rash developed. At first, the bump was the size of a quarter and then grew double in size. The bump finally went down, but the rash she can still see. The rash hasn't grown, it's just there- there is just a red blotch on her arm. She has not had another nose bleed since the one that occurred on 07Apr2021. She just noticed when she had her first dose on 15Mar2021, the nose bleed happened within that week also. The outcome of events was unknown.
COVID19 VACCINE	PFIZER\BIONTECH	1284449-1	65+ years	2 days	Approximately 40 hours after second Pfizer vaccine, patient complained of pain in lower right leg, and a cold foot, lethargy, weakness, feeling unwell. 3 days later, shortness of breath, difficulty breathing, rapid heartbeat, and confusion began. Went to Medical center on 4/20/21, diagnosed with DVT, PE and clots in and around the heart and passed away on 4/21/21 of cardiac shock in the setting of pulmonary and arterial thrombosis.
COVID19 VACCINE	PFIZER\BIONTECH	1286144-1	40-49 years	2 days	Shortness of breath followed by sudden collapse followed by death.

COVID19 VACCINE	PFIZER\BIONTECH	1288414-1	Unknown	2 days	bilateral pulmonary embolism; right DVT; sinus tachycardia; Afib with RVR.; This is a spontaneous report from a contactable physician. This report was received via a sales representative. A 68-year-old male patient received BNT162B2 (Pfizer COVID vaccine), dose 2 via an unspecified route of administration on 09Apr2021 (Batch/Lot Number: Unknown) as single dose for Covid-19 immunisation. Medical history included hypertension, gastroesophageal reflux disease (GERD), and deep vein thrombosis (DVT) original diagnosis from Jan2018. The patient previously received the first dose of BNT162B2 on 19Mar2021 for Covid-19 immunisation. The physician reported the patient had bilateral pulmonary embolism and a right DVT on 11Apr2021. The patient went to the ER on 11Apr2021. She confirms the pulmonary embolisms and the DVT were diagnosed 11Apr2021 when the patient went to the ER. She has more of the patient's story, caller does not think this would be linked to the vaccine but that is for someone else to decide she is reporting. The day of the event the patient's heart was racing, he passed out and went to the ER, he had sinus tachycardia and Afib with RVR (date/s unspecified). His heart rate was up to 140s and 150s. The patient has history of hypertension, GERD, and previous DVT, the original DVT that patient had was diagnosed in Jan2018 and he was placed on Xarelto at that time and he was on Xarelto until Jun2019. He has not been on anything for this since that time, until this episode. Caller says reporter did not provide any specific treatment information that the patient has received for the event she is reporting. Reporter provided the patient went to the emergency room, he did not say if the patient was admitted or had hospitalization. The outcome of events was unknown. Information about the Lot/batch number has been requested.; Sender's Comments: Drug causality would seem unlikely for BNT162B2. The reported events may be regarded as natural progression of patient's pre-existing conditions. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Committees and Investigators, as appropriate.
COVID19 VACCINE	JANSEN	1104152-1	60-64 years	3 days	Developed 3 small blood clots in his left lower leg on Saturday, 3/10/2021 - swelling and slight redness along with pain
COVID19 VACCINE	JANSEN	1117313-1	50-59 years	3 days	Blood clot perpendicular to injection site
COVID19 VACCINE	JANSEN	1201196-1	30-39 years	3 days	Normal side effects until 4/4/21, when chest pressure and pain began at night, with shortness of breath. Appt with Dr on 4/6/21 and was sent for a CTA that confirmed a pulmonary embolism.
COVID19 VACCINE	JANSEN	1201378-1	40-49 years	3 days	Approximately three days after vaccine, I experienced a blood clot. This caused an acute ischemic stroke in my left frontal lobe, resulting in muscle weakness and partial loss of use in my right leg.
COVID19 VACCINE	JANSEN	1202148-1	65+ years	3 days	Began to experience shortness of breath which got worse and worse, until I couldn't walk across a room without being totally out of breath.
COVID19 VACCINE	JANSEN	1202185-1	50-59 years	3 days	Blood clots running down the back of throat. Resolved by the following day.
COVID19 VACCINE	JANSEN	1202661-1	30-39 years	3 days	I woke up 4am on April 6th 2021 to pee and I noticed blood after my pee. There was no blood in my pee or discoloration however I had to clean my penis tip with a tissue and noticed a blood clot came out while I was wiping. This concerns me but that was the only time I saw blood, there was none afterward nor has it occur since then.
COVID19 VACCINE	JANSEN	1203629-1	30-39 years	3 days	Patient developed a DVT four days after vaccination.
COVID19 VACCINE	JANSEN	1204408-1	40-49 years	3 days	I peed some blood clots for 2 days, it was sporadic, not every time I went to the restroom. My urine turned orange.
COVID19 VACCINE	JANSEN	1205996-1	40-49 years	3 days	Nearly a week after injection, injection site is still visibly swollen, slightly warm to touch. Blood clot passed vaginally (outside of normal menstruation schedule).
COVID19 VACCINE	JANSEN	1207703-1	18-29 years	3 days	admitted to hospital for bilateral pulmonary embolism
COVID19 VACCINE	JANSEN	1208077-1	40-49 years	3 days	Flu like symptoms, joint pain, lungs heavy, pain in lungs, headaches - went to ED and PE was found - admitted to ICU - DC'd 5 days later
COVID19 VACCINE	JANSEN	1208555-1	18-29 years	3 days	multiple large blood clots from her nares on Monday 4/12

COVID19 VACCINE	JANSSEN	1210915-1	50-59 years	3 days	Patient seen in ED with CC of unilateral leg pain x3 days. Pt attributes the leg pain developed shortly after receiving the J&J COVID Vaccine. Ultrasound demonstrates superficial thrombosis of greater saphenous vein. Hemodynamically stable. Pt prescribed Eliquis 10mg bid x7 days followed by 5mg po bid. Cannot confirm pt has been administered J&J vaccine -not documented in medical chart, pt only self-reports. Also with sedentary lifestyle/bed-bound.
COVID19 VACCINE	JANSSEN	1212715-1	30-39 years	3 days	Developed pain in right calf and hamstring. No improvement over the next few days. Went to Vein specialist and they performed an ultrasound. A blood clot was found in my right calf.
COVID19 VACCINE	JANSSEN	1213504-1	65+ years	3 days	Deep Vein Blood Clot
COVID19 VACCINE	JANSSEN	1214739-1	40-49 years	3 days	I had the vaccine on Friday then Monday I had a stroke from a blood clot
COVID19 VACCINE	JANSSEN	1215158-1	50-59 years	3 days	Patient developed a blood clot
COVID19 VACCINE	JANSSEN	1219390-1	40-49 years	3 days	Pt states she noticed Tues left leg cramping in calf back and knee and thigh that feels like a charlie horse. denies hx of blood clots or long travel Left calf swollen cool to touch. Pt states her foot is more swollen to her. Patient found to have an indeterminate age deep vein thrombosis. Discharged home from the emergency department with a prescription for Apixaban.
COVID19 VACCINE	JANSSEN	1221553-1	30-39 years	3 days	PE. Pt was placed on therapeutic Lovenox and supplement oxygen which was weaned off and pt discharged home.
COVID19 VACCINE	JANSSEN	1223967-1	65+ years	3 days	On March 1st, I had a sonogram of the veins in both of my legs and nothing was found, on March 5th I received the COVID-19 vaccine after standing in line for 2&1/2 hours. By March 8th the swelling and pain in my left leg was so bad I made an appointment with Dr. for March 11th. He ordered another sonogram and found 2 DVTs in my left leg, and prescribed anti-coagulants which I am still on. At the time the Doctor said that this was most likely a result of having stood in line for 2&1/2 hours.
COVID19 VACCINE	JANSSEN	1224238-1	30-39 years	3 days	Left leg pain Mild Chest pain (resolved)
COVID19 VACCINE	JANSSEN	1226730-1	65+ years	3 days	Big blood clots following Prostate Surgery 3 days after Vaccine applied Please see attached explanation and pictures
COVID19 VACCINE	JANSSEN	1228304-1	60-64 years	3 days	I was ill with diarrhea, sick to stomach, blood clots coming out of my rectum for 24 hrs., body aches.
COVID19 VACCINE	JANSSEN	1228903-1	65+ years	3 days	patient had massive intracerebral hemorrhage 3 days after vaccination. family claims patient was doing well until vaccination. there is a suspicion that patient might have had sinus venous thrombosis that lead to the the ICH.
COVID19 VACCINE	JANSSEN	1230134-1	40-49 years	3 days	Started to feel chest pain and shortness of breath 3 days after the vaccine. Ended up in the hospital 5 days after the vaccine and diagnosed with blood clots in the lungs.
COVID19 VACCINE	JANSSEN	1231210-1	50-59 years	3 days	I received the vaccine on 3-12-21 and woke up 3-15-21 with pain in the bottom of my left foot. I scheduled an apt with my PCP on 3-16-21. My PCP scheduled an ultrasound on 3-24-21 where the nurse discovered blood clots in my lower left leg. I started taking Eliquis later that afternoon. I then had an apt with a blood dr. on 4-9-21 where she drew blood for tests. I was experiencing my heart racing and she scheduled me an apt with a cardiologist on 4-13-21 where the cardiologist suspected that the clots had moved into my lungs. The cardiologist did an EKG on the same day. I have a heart echo scheduled for 5-7-21. I am experiencing side effects from Eliquis so 4-19-21 I switched to Xeralto.
COVID19 VACCINE	JANSSEN	1234907-1	65+ years	3 days	On April 16 patient came home fatigue, pale and legs hurting. The next day complained of right knee pain, Fatigue and looked pale. He woke up in the middle of the night complaining of right calf tightness and pain. On Sunday 18th he started to limp and when we looked at his calf it was double in size, warm to touch, and redness. We then went to the ER and had an ultrasound and CT scan. We were told he has multiple blood clots in the right leg and clots in both lungs. He was then transported to a hospital and given blood thinner shots in stomach. He was released from the hospital 4/20 and given blood thinners and assigned a hematologist. He'll be on blood thinners 6-12 months, out of work a month and tested regularly to check platelets.
COVID19 VACCINE	JANSSEN	1237452-1	18-29 years	3 days	Acute deep vein thrombosis (DVT) of right peroneal vein

COVID19 VACCINE	JANSSEN	1242493-1	40-49 years	3 days	On March 13, I received the Johnson & Johnson vaccine at the clinic. The pharmacist monitored me for symptoms but there were none right away. I did have a fever and some body aches in the two or three days that followed but those were short-lived. While driving on March 16, I started experiencing some irregular breathing and periods of shortness of breath about three hours after leaving home. I stopped at the emergency room at the Health Center where Dr diagnosed me with an acute pulmonary embolism after discovering a small blood clot in one of my lungs. He prescribed me with Eliquis, which I am still taking today. Their phone number is provided if you have questions. I haven't had too many shortness of breath episodes lately but do not know if the blood clot is still there. I am scheduled to see my hematologist on April 27 to get further updates on this. My hematologist Dr is located in clinic number provided. While it has not yet been proven that the vaccine caused the blood clot in my lung, I feel the need to report this in the wake of recent news about the Johnson & Johnson vaccine. My hematologist and primary care physician are both aware that I have received the vaccine but I have not received any further communication from them.
COVID19 VACCINE	JANSSEN	1243646-1	65+ years	3 days	On Sunday night, 04/11/2021 around 7:00pm, patient stated she started getting sick to her stomach. She complained of headaches and fatigue. At midnight she vomited, couldn't lay down and symptoms lasted all night. She complained of back pain too. she noticed blood in her urine with a clot of blood in it and had shortness of breath. She vomited twice. In contact by phone with her daughter at the time. Patient refused to go to the emergency room or call her physician. She has a cardiologist who is her primary care physician.
COVID19 VACCINE	JANSSEN	1244060-1	65+ years	3 days	Patient received the vaccine on 4/10/21 and a few days later hit his leg, which subsequently became erythematous and swollen. He went to urgent care on 4/13/21 and received a prescription for doxycycline which he stopped taking prior to resolution of symptoms due to side effects from the medication. He was prescribed clindamycin, but did not start this medication. Patient had outpatient labwork this morning which revealed an elevated SCr, for which he was sent to the ED. The patient was found to have AKI with hyperkalemia, as well as left lower extremity DVT and cellulitis. Patient is being treated with heparin and linezolid, as well as Kayexalate. The patient is being admitted to the hospital for treatment.
COVID19 VACCINE	JANSSEN	1251620-1	65+ years	3 days	Severe pain in left thigh groin & knee area. Went to ER, confirmed blood clot. Sent home w/blood thinners - Xarelto
COVID19 VACCINE	JANSSEN	1251931-1	30-39 years	3 days	Right peroneal vein DVT
COVID19 VACCINE	JANSSEN	1258007-1	18-29 years	3 days	diagnosed with transverse sinus thrombosis, outcome unknown transferred to Hospital upstate
COVID19 VACCINE	JANSSEN	1259672-1	65+ years	3 days	Pt received Janssen vaccine on 4/5/21 and did complain of arm soreness on 4/6/21. Arm assessed small bruising noted. Pt working with therapy on 4/8/21- she was complaining of pain, nsg assessed arm and found the RUE was blue in color and hard to touch. NP made aware, ordered warm compresses as needed to arm. MD assessed pt on 4/9/21 for a poss. UTI- IV Rocephin ordered and adm. Pt had an allergic reaction to IV Rocephin, pt sent to ER for eval and treatment. Pt was adm on 4/9/21 and returned to health on 4/15/21. When pt arrived her entire rt arm/hand is black in blue in color. Per patient and daughter- the bruising continued to get worse day by day after she had received the vaccine
COVID19 VACCINE	JANSSEN	1260342-1	40-49 years	3 days	Patient came in this evening 4/26 after emergency room visit for blood clot in leg/shin. She received Janssen IMZ 4/10. Her symptoms of painful leg began several days after her IMZ and continued to worsen with her leg shin swollen, painful, bruised with a knot until she sought medical help in the ER. Ultrasound was done and ruled out deep vein thrombosis, determined to be peripheral blood clot. She was sent home on meloxicam for pain and inflammation.
COVID19 VACCINE	JANSSEN	1270837-1	50-59 years	3 days	a few days after the shot i was having a hard time breathing, made appointment with Pulmanologist he ordered a ct scan but no ultra sound. ct scan showed no clots in the lungs at that time. Woke up a day or two later with severe back and leg pain was transported to the emergency room. I was then transported to facility because i could not move my left leg and was in severe pain. During my stay i coughed up a blood and requested the doctor to do blood work. The blood work showed high levels of clots. I was not taken to the hospital or treatment for the clots at that time. When i left the facility i saw my Doctor she ordered immediatly another ct scan of the chest and an ultra sound

COVID19 VACCINE	JANSEN	1271366-1	60-64 years	3 days	Patient was seen in my office by me on April 27th. She reports having left leg pain discomfort which started 3 days after receive Johnson and Johnson COVID vaccine. She denies swelling or any other associated symptoms. I ordered Venous Duplex which was done today and revealed b/l femoral DVT. Patient immediately started on Eliquis .
COVID19 VACCINE	JANSEN	1273486-1	60-64 years	3 days	Patient developed cold symptoms with heavy drainage on 4/15/21. Patient took a whole package as directed but continued to get worse. Used Vicks Vapor Rub and took a couple doses of sinus medication after the Coriadin was gone. Started severely hurting with difficulty breathing and chest pain on 4/27/21. Went to The Hospital on 4/28/21. Was diagnosed with pneumonia, pulmonary embolism in left lower lobe pulmonary arterial branches. Patient was admitted. Patient placed on Rocephin 1 gram IVPB daily and azithromycin 500 mg IVPB daily. Patient was started on therapeutic dosing of Lovenox and then transitioned to Eliquis 10 mg BID for 7 days then 5 mg BID. See hos.
COVID19 VACCINE	JANSEN	1273615-1	40-49 years	3 days	A few days after the vaccine my leg became complete cramped which caused me to go to the ER where several testwere performed and a vascular X-ray was also performed where it revealed a DVT was present in my lower left leg. I am currently taking Eliquis and various additional testing has been done to see why this has occurred but are pending the results. I still have edema and the minor cramping in my leg and foot also.
COVID19 VACCINE	JANSEN	1274597-1	50-59 years	3 days	Three days after receiving the vaccine, he developed a headache which was intermittent with pain score of 5-8 out of 10. Headache became consistent around 4/11/21. Pain is in the occipital region and occasionally radiates behind the eyes. Also complains of dizziness, nausea, vomiting, and tingling in his hands bilaterally - worse in the mornings and goes away after waking up. He presented to Medical Center on 4/28/21 and transferred to Medical Center for treatment of vaccine induced thrombocytopenia and nonocclusive straight sinus thrombus. He was started on bivalirudin infusion 4/29 @ 0142 via continuous infusion. Still receiving treatment at the time of this report.
COVID19 VACCINE	MODERNA	0919376-1	18-29 years	3 days	Patient received Moderna vaccine, Wednesday 12/30. On Saturday 1/3/2021 patient felt pressure/tightness in lower extremity. When patient touched area, a noticeable ball was felt under the skin, tender to the touch and warm. Patient went into urgent care on Monday 1/4/2021 with a confirmed dx of a superficial blood clot. Unknown etiology of whether this is from current birth control or the COVID19 Moderna vaccine.
COVID19 VACCINE	MODERNA	0968867-1	65+ years	3 days	Developed swelling of left lower leg on 1/24/2021, went to ED and was diagnosed with DVT of the L femoral vein. Placed on Xarelto and sent home.
COVID19 VACCINE	MODERNA	0969093-1	65+ years	3 days	Pt received vaccine and within 72 hrs developed a stroke. Low platelet count. Endocarditis. Emboli to liver, spleen, kidney.
COVID19 VACCINE	MODERNA	0978912-1	65+ years	3 days	Large, bilateral, unprovoked pulmonary emboli 3 days after a Moderna first dose vaccine in a patient with no risk factors for DVT or PE and no history of any sort of pro-thrombotic disorder. He is in the hospital and work up is in progress, and so we might find another reason for his PE, but as of now we have no other explanation.
COVID19 VACCINE	MODERNA	0992338-1	30-39 years	3 days	Pulmonary embolism, with pulmonary infarct
COVID19 VACCINE	MODERNA	1032165-1	30-39 years	3 days	2/6 I had the 2nd Moderna vaccine. On 2/7-2/8 I had body aches, chills, and 99.4F temp. On 2/9 those symptoms subsided, but I started to get right-sided flank pain with pain on inhalation. I took acetaminophen and ibuprofen around the clock, used a heating pad on 2/9 and 2/10, but pain progressed. Mid-day on 2/10 the pain was so severe, I went to urgent care. They said it was gastritis and released me. I went back 2 hours later and saw a different doctor. He diagnosed me with a pulmonary embolism, pulmonary infarction, and pleural effusion. I was sent by ambulance to the hospital and admitted. I was treated for pain and started on Eliquis. I was discharged the evening of 2/12. The morning of 2/13, I woke up with 100.6 F Temp and 85% O2 at. I went to urgent care again, they thought I had pneumonia and referred me to the hospital. I was admitted to a different hospital on 2/12 and continue to antibiotics and a heparin drip
COVID19 VACCINE	MODERNA	1036200-1	50-59 years	3 days	Patient developed chest pain and was admitted to ED with pulmonary embolism.
COVID19 VACCINE	MODERNA	1053191-1	65+ years	3 days	Vaccine administered 02/08/2021 , by Thursday 02/11/2021 patient almost nonverbal, by Monday 02/15/2021 patient went to the hospital with bruising, sores on her stomach and clots reported as thrombocytopenia, deceased by Friday 02/19/2021.

COVID19 VACCINE	MODERNA	1056011-1	65+ years	3 days	My grandpa had a stroke on the 15th of February. He claimed he had been feeling ""off"" for a few days, but didn't say anything. A blood clot had formed in his brain. He was doing better and about to go to rehab to strength his right side of his body. On the 22nd he took a turn for the worst. He was having trouble breathing and they sedated and partially paralyzed him to put a tube in his mouth. I believe another blood clot had formed and oxygen wasn't properly going through his body. They could not stabilize him, and he passed away the same day.""
COVID19 VACCINE	MODERNA	1067360-1	50-59 years	3 days	Bleeding in urine started on days 3, 4, and 5 after the injection. Blood in urine cleared up on approximately the 6th day post injection.
COVID19 VACCINE	MODERNA	1074792-1	65+ years	3 days	2/12 Patient presented with palpitations, sensation of heat with no chest pain. Of note patient had covid diagnosed 11/20. Work up showed saddle PE and had SVT treated with adenonsine. Treated with IV heparin. Patient on 2L O2 weaned to room air before discharge. Patient transferred to CIRS 2/17. Per EAU, hospitalizations are to be reported irrespective of attribution to the vaccine.
COVID19 VACCINE	MODERNA	1103161-1	40-49 years	3 days	DVT. Symptoms began on 2/19, diagnosed in hospital formally on 2/21.
COVID19 VACCINE	MODERNA	1104062-1	40-49 years	3 days	Three days after initial Moderna Vaccine, I developed signs and symptoms consistent with DVT. I presented to my PCP's office for evaluation on Thursday; February 4 and was sent for an ultrasound at Imaging. Ultrasound of right leg showed 2 DVT's. I was started on Pradaxa but experienced an adverse reaction (excessive bleeding with menstruation) which resulted in an emergency room visit on 2/8/2021 and 2 additional days of prescribed bed rest.
COVID19 VACCINE	MODERNA	1105310-1	50-59 years	3 days	Began having SOB 3 days post immunization. worsened over then next 2 days when she was seen in clinic and sent for CT angio where submassive PE was discovered and she was experiencing significant right heart strain which led to hospitalization. while hospitalized additional DVT was discovered. received catheter directed TPA. now on likely lifelong xarelto
COVID19 VACCINE	MODERNA	1105496-1	65+ years	3 days	you got second Moderna vaccine on March 10, Wednesday. Saturday night began with left leg swelling and pain. Thought it was a side effect of the vaccine. Tuesday, march 16 the pain got so bad he went to ER. Has bleed clots in main artery in leg femoral artery. Pt. was transferred to larger hospital.
COVID19 VACCINE	MODERNA	1109272-1	40-49 years	3 days	pulmonary embolus onset 3 days post 1st dose Moderna vaccine
COVID19 VACCINE	MODERNA	1115502-1	65+ years	3 days	Pulmonary embolism now on anticoagulants
COVID19 VACCINE	MODERNA	1125249-1	Unknown	3 days	Two blood clots in the posterior lobes of her lung; heart rate was really fast; A spontaneous report was received from a 69 year-old female consumer who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced two blood clots in the posterior lobes of her lung and heart rate was really fast. The patient's medical history included diverticulitis. Consumer mentioned that she was recovering from diverticulitis when she received the first Moderna vaccine. Products known to have been used by the patient, within two weeks prior to the event, included flagyl, bactrim, clindamycin (for a dental procedure one day after her vaccine), famotidine, lorazepam and elavil. On 09 Feb 2021, four days prior to the onset of the events, the consumer received their first of two planned doses of mRNA-1273 (lot/batch: 030M20A) intramuscularly in left arm for prophylaxis of COVID-19 infection. On 12 Feb 2021, the consumer experienced really fast heart rate and went to urgent care. The patient was referred to the hospital where it was found that the patient had two blood clots in the posterior lobes of her lung and she was hospitalized. Treatment for the event included heparin bolus (dose and duration) not specified. The patient was discharged on 13 Feb 2021 and started on Eliquis 5 mg twice a day. Action taken with mRNA-1273 in response to the events was unknown. The outcome of the events was resolved. The assessment for the events was not provided.; Reporter's Comments: Very limited information regarding the events has been provided at this time. Further information has been requested.

COVID19 VACCINE	MODERNA	1133481-1	65+ years	3 days	Blood clot in his left lung and right lung; Blood clots in his right groin; Terrible pain on the left side of his upper body,It hurts so much; A spontaneous report was received from a consumer concerning a 78 years old male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced terrible pain on the left side of his upper body, it hurt so much, blood clot in his left and right lung and blood clots in right groin. The patient's medical history was reported by the reporter as high blood pressure, prediabetes and hepatitis C due to a bad blood transfusion (treated with Mavyret). Concomitant medication was not reported. On 11 Feb 2021, three days prior to the onset of the event, the patient received their first of two planned doses of mRNA-1273 (Lot number: 031L20A) through an unknown route at left arm for prophylaxis of COVID-19 infection. On 14 Feb 2021, 3 days after vaccination, patient had a terrible pain on the left side of his upper body and was hospitalized, the tests revealed blood clot in his left and right lung as well as in right groin, which was treated by Eliquis. Patient was observed overnight and discharged with a follow up in 3-6 months. Action taken with mRNA-1273 in response to the events was unknown. The reporting physician assessed the events as not related to the product, but did not recommend second of vaccine. The outcome of events was unknown.; Reporter's Comments: Based on reporter's causality and history of diabetes and Hepatitis C infection, the event is assessed as unlikely related to mRNA-1273.
COVID19 VACCINE	MODERNA	1137940-1	65+ years	3 days	About 11:30 PM on 03/15/2021, started gasping for breath when laying down, sat up in lazy boy for a hour and half, beathing returned to normal. About 3:30 PM on 3/16/2021, started gasping for breath again. Called my daughter and she transported me to Hospital. They tested for covid - results negative. They did a C-Scan of my chest and saw a blood clot in each lung. While hooked to the monitors, they found I had Afib. They also did an ultra-sound of my legs and found a small clot in each leg below the knees in a small vein. I have never had any record of clots or Afib. They transferred me to Medical Center early on 3/17/2021. They started a heparin drip to soften the clots. In the afternoon of 3/17/2021, they performed a Suction Thrombectomy to remove the clots from my lungs. On 3/19/2021, they put me on Eliquis Tab. I was released from the hospital in the evening of 3/20/2021.
COVID19 VACCINE	MODERNA	1155485-1	65+ years	3 days	About 3 days after the vaccine my daughter mentioned to me that I was not breathing right. It was harder to breathe and I could not even take a shower that I would be out of breath. My daughter checked my pulsox and it was 85. I couldn't really walk or do anything so my daughter transported me to ER and lots of labs were done so since my D Dimer was too high they did a CT scan and it showed some blood clots in my lungs. They admitted me because they were concerned with the location of one of them. They did some heart tests too and put me on Eloquis and then sent me home. I stayed for 2 days. Then they scheduled me FUs with a heart doctor and a pulmonologist.
COVID19 VACCINE	MODERNA	1157586-1	65+ years	3 days	Pulmonary embolism; Shortness of breath; A spontaneous report was received from a physician, concerning a 67 years old female patient, who received Moderna's COVID-19 vaccine and experienced shortness of breath and pulmonary embolism. The patient's medical history was not provided. Concomitant product details were not provided by the reporter. On 15-Feb-2021, prior to the onset of events, the patient received her first of two planned doses of mRNA-1273 (lot number unknown) via intramuscular route for COVID-19 infection prophylaxis. On 15-Mar-2021, after the recovery from the events, the patient received her second of two planned doses of mRNA-1273 (lot number unknown) via unknown route for COVID-19 infection prophylaxis. On 18-Feb-2021, after first dose of vaccine, the patient experienced shortness of breath and required 2 days hospitalization for pulmonary embolism. Treatment using Enoxaparin was reported. The shortness of breath was gone once being discharged from the hospital. Rivaroxaban was prescribed as the discharge medication. Action taken with mRNA-1273 in response to the event was not applicable. The outcome of the events shortness of breath was considered resolved and of event pulmonary embolism was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

COVID19 VACCINE	MODERNA	1162004-1	Unknown	3 days	pulmonary embolism; shortness of breath; A Spontaneous report was received from physician concerning a female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and had pulmonary embolism and shortness of breath. The patient's medical history was not reported, and concomitant medication included Albuterol, Lipitor, Flonase, Synthroid, loratadine, metoprolol and Torsemide. On 24 Feb 2021, 1 day prior to the onset of the event, the patient received their first dose mRNA-1273 (Lot number: unknown, Expiration date: not provided) via intramuscular route for prophylaxis of COVID-19 infection. On 27 Feb 2021, after administration of vaccine patient experienced shortness of breath. On an unknown date patient experienced pulmonary embolism and was admitted for three days. She was given Heparin and Coumadin. She was admitted for three days and was sent home with a prescription for Lovenox and Warfarin. Action taken with the mRNA-1273 in response to the events was not provided. The outcome were recovered for events.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1166586-1	40-49 years	3 days	Pericardial Effusion Bilateral Pulmonary Embolism
COVID19 VACCINE	MODERNA	1179621-1	40-49 years	3 days	Patient reported DOE March 4, 2021, was subsequently diagnosed with pulmonary embolism, hospitalized and treated with Xarelto. He is currently recovering and will continue with Xarelto as an outpatient.
COVID19 VACCINE	MODERNA	1182802-1	65+ years	3 days	pain in legs on 3/22/21
COVID19 VACCINE	MODERNA	1188223-1	65+ years	3 days	3/16/2021 Received 2nd Moderna Covid-19 vaccine 3/25/2021 Trouble breathing when exercising so stopped after 5 min and usually do 20 mim; temp elevated for me normal 97.6 and was between 98.6 and 99.3, hacking up yellowish phelgm. Phelgm had been coming up for longer period of time. 3/26/2021 went to clinic and put on treatment for possible bronchitus. Z-Pak and Prednisone 5 days and asked to schedule x-ray to see if something more showed. 3/30/2021 Completed meds and x ray scheduled. No improvement in breathing 4/1/2021 was finally able to get chest x-ray 4/2/2021 x-ray showed nodule on lung & calcified grandular - told to schedule ct to check out nodule - told clinic still no change in condition 4/5/2021 called clinic again due to pain overnight in left lung. Trouble getting ct scheduled so clinic sent to me emergency room rather than schedule ct 4/5/2021 - At ER blood work, x-ray and ct scan completed. CT chest was significant for large bilateral pulomanry emboli w r ventricular strain. Also r middle lobe lung nodule and r adrenal nodule. Started on heparin drip and admitted. Hospitalized 4/5 and sent home 4/8. Sent home on Xarelto to continue at least 3 months and consult w family doctor to determine cause of submassive clots and further treatment.
COVID19 VACCINE	MODERNA	1203230-1	30-39 years	3 days	Initially I had arm soreness at the area of the shot. Saturday evening following the vaccine I had pain in my left side of the neck. Sunday the pain went from the left side of my neck down to the base of my ribs and then progressed to include the back and chest almost constantly instead of just on inhalation. I went to the ER on Sunday evening, assuming very bad costochondritis; however, was diagnosed with multiple pulmonary embolisms in the left lung, areas of possible infarction, and pleurisy. I had a CT scan at a Medical Center prior to receiving the Moderna vaccine for a suspected PE and it was negative.
COVID19 VACCINE	MODERNA	1204717-1	60-64 years	3 days	On February 5th, I received my second Moderna vaccine. Monday the 8th, I was working from home and wasn't feeling well. I went to lay down and was not able to. It was hard to breath. I got up, went to another room where there was a recliner and sat in it trying to catch my breath. It got harder to breathe. I had my husband call 911. I went to the ER, had a CT scan of my chest and was found to have ?extensive PE?s?, ground glass and signs of pneumonitis. I was admitted to the CICU for two days and was transferred for two days. I was told by my orthopedic surgeon that there was a high unlikelihood of PE?s developing from my ankle fracture 3 months later. I had home health care for approximately one month.

COVID19 VACCINE	MODERNA	1205849-1	65+ years	3 days	3/13/2021: Red rash/hives on arms, neck, scalp, chest, back / was treated at ER with benedryl, given albuterol inhaler to take 2 puffs, 4X day for 7 days; prednisone, 40mg daily for 5 days 3/16/21: had mini stroke at home, called ambulance, they administered a series of tests and determined that all his vital signs were normal and asked if he wanted to go to hosp for add'l testing and pt refused. 3/17/21: had 2nd mini stroke in vehicle, went straight to Hosp ER and was admitted. CT scan and MRI determined that I had suffered 2 strokes due to blood clots in the rt side of brain. Was told to take 325 mg of aspirin a day and released on 3/19/21 with instructions to f/u with PCP and Neurologist. PCP recommends that I should NOT take the 2nd dose of the Moderna vaccine.
COVID19 VACCINE	MODERNA	1205967-1	50-59 years	3 days	Swelling of the legs began on the 28th of February, Patient went to ER on March 7th and diagnosed with DVT. Patient was discharged about 12 hours after arrival and put on rivaroxaban. Patient returned to the ER on March 13th and was diagnosed with bilateral Pulmonary Embolism patient was kept overnight put on heparin drip and then transitioned to rivaroxaban. Patient does not know if the vaccine was the cause as patient has had 2 previous DVT's (no previous PE's). DVT's both occurred after transcontinental flights. This recent DVT and PE occurred with no know reason. Patient is positive for Leiden5
COVID19 VACCINE	MODERNA	1207337-1	40-49 years	3 days	FINAL DIAGNOSIS: o Acute pulmonary embolism and DVT SECONDARY DIAGNOSIS: Principal Problem: Pulmonary embolism and infarction (CMS/HCC) POA: Yes Active Problems: Tobacco abuse POA: Yes Opioid dependence (CMS/HCC) POA: Yes Pulmonary embolism (CMS/HCC) POA: Unknown DVT (deep venous thrombosis) (CMS/HCC) POA: Unknown Chest pain POA: Unknown Hemoptysis POA: Unknown Resolved Problems: * No resolved hospital problems. * PDMP Query Date: 03/24/21 PDMP Comments: 03/22/21 suboxone 8mg/2mg #14/14 days multiple fills BRIEF HOSPITAL COURSE: a 44 year old male with h/o of anxiety, depression, substance use on Suboxone, history of alcohol abuse, admitted 3/24/2021 with pleuritic chest pain and shortness of breath. Evaluation was positive for bilateral DVT and pulmonary embolism Bilateral PE, infarction, bilateral DVTs -No obvious precipitating factors -patient underwent first COVID 19 vaccine injection, is actually due for second shot. Unclear if this is contributed, recommended to hold on getting second dose and discuss this with PCP. -Also follow-up with PCP for appropriate cancer screening - patient was treated with therapeutic subcutaneous Lovenox, remained hemodynamically stable and is feeling better today. Upon discharge we'll prescribe Elocon is 10 mg b.i.d. for another 5 days followed by 5 mg b.i.d. maintenance dose. He will be provided with coupon for 1 month supply, he was recommended to follow-up with PCP for further recommendations. He will probably need anticoagulation for at least 6 months or longer depending on further course. -Echocardiogram showed ejection fraction 50-55%, Mild mitral valve prolapse no evidence of RV strain. Hemoptysis -Most likely was related to PE and infarction -resolved. Pleuritic chest pain, h/o Afib -Most likely pain was secondary to PE, improved -Continue Cardizem as prior to admission -Stop aspirin since patient will be on anticoagulation therapy History of opioid dependence, alcohol abuse Continue suboxone Ongoing smoking smoking cessation was advised Disposition: Routine Discharge Home CONSULTS: Consults Ordered during this Encounter Procedures ? Ancillary Service Request - IV Team New IV Start (multiple sticks for labs) ? Ancillary Service Request - Social Services PROCEDURES: Procedures Ordered during this Encounter Procedures ? Patient is currently on therapeutic anticoagulation (warfarin, Pradaxa, IV heparin, Rivaroxaban) - no reassessment RADIOLOGY TESTS: CT CTA Chest Final Result 1. Segmental and subsegmental pulmonary emboli throughout the right lung, most prominent in the right lower lobe. Segmental and subsegmental pulmonary artery the left pleural effusion. 2. Wedge-shaped opacities at both lung bases concerning for small pulmonary infarcts. 3. No findings of right heart strain or pulmonary hypertension. Impression discussed with Dr of the ER at 20:44 on 03/24/2021 by phone. Electronically signed by: MD 3/24/2021 8:46 PM US Legs Bil Venous DVT Final Result Bilateral posterior tibial vein thrombosis. This critical result was called to the clinical team, including by telephone, at 6:00 PM by the sonographer, according to internal Department documentation. Electronically signed by: MD 3/24/2021 6:16 PM XR Chest PA and Lateral Final Result Small bilateral pleural effusions. Streaky left basilar opacity may reflect atelectasis or infiltrate. Small right basilar opacity of uncertain significance. All opacities are new since 2016. No pneumothorax. 4 week follow-up is recommended. If the abnormalities have not resolved by then,
COVID19 VACCINE	MODERNA	1208579-1	65+ years	3 days	Developed blood clot in heart --> went into Atrial Fibrillation with no prior history of A Fib --> Large clot was thrown from the heart into the brain splitting into two clots, one blocking brain stem and one blocking right hemisphere --> Death on 2/10/21

COVID19 VACCINE	MODERNA	1208654-1	65+ years	3 days	Patient presented 3 days after her second DuoNeb vaccine with weakness dizziness chest pain or shortness of breath and was initially diagnosed with a pneumonia by chest x-ray obtained with antibiotics without improvement. Subsequently she was hospitalized and CT of the chest showed left lower lobe segmental pulmonary embolism. The patient never had history of venous thromboembolism in the past. She had weakly positive anticardiolipin antibody of IgG type of unknown significance. She was treated initially with antibiotics but after diagnosis of the blood clot she was started on anticoagulation with apixaban with improvement
COVID19 VACCINE	MODERNA	1208878-1	65+ years	3 days	Two blood clots in right lung two days after second vaccine. I was hospitalized and I am now on oxygen 24/7 and I'm taking blood thinner Eliquis.
COVID19 VACCINE	MODERNA	1211176-1	65+ years	3 days	walked a mile a day and has always taken care of himself. He ran marathons. He never was bothered by walking the daily miles. Nothing happened while he walked even though he has a sarcoma. One night, after he got into bed, his hip and leg started hurting and have continuously hurt since then. His pain is debilitating and his leg is very heavy. He can not lift his leg to get into bed. His wife has to lift it with two hands. He cannot lift his leg to get into a car. He has been given Gabapentin, Norco, Tramadol, and Tylenol for pain. He needs ice packs during the day and night. He cannot sleep in his bed all night. He has gotten up to sleep in a recliner.
COVID19 VACCINE	MODERNA	1212827-1	65+ years	3 days	THREE DAYS AFTER GETTING HIS 2ND DOSE OF MODERNA THE PATIENT DEVELOPED SOB AND WAS FOUND TOP HAVE BILATERAL PULMONARY EMBOLISM AND DVT
COVID19 VACCINE	MODERNA	1213415-1	50-59 years	3 days	56 year old gentleman with only medical history being COVID-19 infection in October. Admitted on 4/13/2021 for a cerebral vascular accident due to thrombosis of right posterior cerebral artery hemorrhagic conversion (I63.331). Has left-sided weakness. Patient also tested positive by PCR (Panther Aptima) on 4/14/2021.
COVID19 VACCINE	MODERNA	1214747-1	18-29 years	3 days	Patient admitted 4/14/2021 with chest pain. Patient had received second Moderna vaccine on Sunday 4/11/2021 Patient had pain underneath both armpits. Patient was woken up around 4AM due to substernal pressure-like chest pain, left sided. Admitted through the ED. Cardiac Cath on 04/14/2021. Non-ST segment elevation myocardial infarction mostly likely secondary to maternal vaccine and acute thrombosis. 4/14/2021 Troponin I High Sens 3288 @ 0735 and 7616 @0930.
COVID19 VACCINE	MODERNA	1242376-1	60-64 years	3 days	Vaccine on 04/10/21.Shortness of breath, dizziness, nausea 04/13/2021. Death on at hospital on 04/14/2021 Autopsy found Bilateral pulmonary thromboembolus

COVID19 VACCINE	MODERNA	1245376-1	Unknown	3 days	<p>CT with contrast emergently done this Sunday 11Apr2021 revealing Mid right lobe pulmonary; Experienced pleural pain; chest ""Feels like a broken limb; This spontaneous case was reported by a nurse (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (CT with contrast emergently done this Sunday 11Apr2021 revealing Mid right lobe pulmonary) in a 64-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Diabetes, Stenosis (cervical spine stenosis), Carcinoma (on face) and Vomiting (Vomited every other day for 2 weeks straight after 1st dose. ). Concomitant products included ASPIRIN [ACETYSALICYLIC ACID] for Prophylactic. On 08-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 11-Apr-2021, the patient experienced PULMONARY EMBOLISM (CT with contrast emergently done this Sunday 11Apr2021 revealing Mid right lobe pulmonary) (seriousness criterion medically significant), PLEURITIC PAIN (Experienced pleural pain) and CHEST DISCOMFORT (chest ""Feels like a broken limb). At the time of the report, PULMONARY EMBOLISM (CT with contrast emergently done this Sunday 11Apr2021 revealing Mid right lobe pulmonary), PLEURITIC PAIN (Experienced pleural pain) and CHEST DISCOMFORT (chest ""Feels like a broken limb) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Apr-2021, Computerised tomogram: unknown (Inconclusive) ct scan with contrast revealed Mid right lobe pulmonary embolism. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment included as heavy thrombolytics. Based on the current available information and the temporal association between the product use and the start date of the events a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-075787 (E2B Linked Report); Sender's Comments: Based on the current available information and the temporal association between the product use and the start date of the events a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-075787:Case for first dose""</p>
COVID19 VACCINE	MODERNA	1245460-1	65+ years	3 days	<p>I had a stroke; Blood clot; Speak was bad, couldn't form words, speak was impaired; Missed her dose due to to the decision not to get it; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of CEREBROVASCULAR ACCIDENT (I had a stroke) and THROMBOSIS (Blood clot) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 010M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history was reported.). On 10-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 13-Feb-2021, the patient experienced CEREBROVASCULAR ACCIDENT (I had a stroke) (seriousness criterion hospitalization). On an unknown date, the patient experienced THROMBOSIS (Blood clot) (seriousness criterion medically significant), SPEECH DISORDER (Speak was bad, couldn't form words, speak was impaired) and INTENTIONAL DOSE OMISSION (Missed her dose due to to the decision not to get it). On 16-Feb-2021, CEREBROVASCULAR ACCIDENT (I had a stroke) had resolved. At the time of the report, THROMBOSIS (Blood clot) and SPEECH DISORDER (Speak was bad, couldn't form words, speak was impaired) outcome was unknown and INTENTIONAL DOSE OMISSION (Missed her dose due to to the decision not to get it) had resolved. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant product use was not provided. The patient was receiving treatment with clopidogrel (Plavix) 75mg since the stroke (which is a stronger blood thinner TPA drug that resolve the blood clot). Reportedly, the patient was hospitalized for 3 days. Patient also stated that she was nervous about getting her 2nd dose so she missed her dose due to the decision not to get it with regards to the fear of having another stroke. Company comment Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked; Sender's Comments:</p>

COVID19 VACCINE	PFIZER\BIONTECH	0925644-1	65+ years	3 days	Confirmed DVT in the left leg; COVID test (PCR swab): positive on 26Dec2020; COVID test (PCR swab): positive on 26Dec2020; This is a spontaneous report from a contactable other healthcare professional. An 85-year-old female patient received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# ELO140, expiration date: Mar2021), via an unspecified route of administration in arm (deltoid; unknown side) on 23Dec2020 at single dose for Covid-19 immunisation. Medical history included type 2 diabetes mellitus from 2017 and ongoing, high blood pressure from 2017 and ongoing, atrial fibrillation (A-Fib) from 2019 and ongoing. The patient's concomitant medications were not reported. The patient was administered first dose of the COVID vaccine on 23Dec2020 and then was swabbed for COVID on 26Dec2020, and then on 28Dec2020 her PCR swab was positive for COVID. She was asymptomatic until she started complaining of leg pain. She ordered an ultrasound for the patient on 30Dec2020, and it confirmed a deep vein thrombosis (DVT) in left leg. The patient was being treated with anticoagulant apixaban (ELIQUIS) currently. Caller stated that this could be that it (DVT) is from COVID, but her real question was, could it be from the vaccine? In Pfizer's information packet for patients, there is section on what to tell your provider prior to getting vaccinated. One of the things on there is if you have a bleeding disorder or are on an anticoagulant. There is no explanation as to why it was in the packet of information. Caller has looked everywhere and can not figure out why that is on the FAQ/packet information. The patient was due for the second dose on 13Jan2020, but she was worried and hesitant to approve it. The patient underwent lab tests and procedures which included COVID test (PCR swab): positive on 26Dec2020, ultrasound of the left leg: confirmed DVT on 30Dec2020. The outcome of events was not recovered.; Sender's Comments: There is not a reasonable possibility that event ""COVID test (PCR swab): positive"" is related to BNT162B2 vaccine. The event occurred 3 days after vaccination, when vaccine was not expected to achieve the effect. The event DVT of legs is not considered related to BNT162B2 vaccine. The patient had underlying diabetes and cardiovascular disorders, which are considered as risk factors for DVT. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.""
COVID19 VACCINE	PFIZER\BIONTECH	0934028-1	30-39 years	3 days	Patient received her covid vaccine on 12/28/2020 in her left arm. Three days after vaccination she had pain and swelling in her right arm. She was seen by a health care provider on 12/31/2020 and an ultrasound showed extensive deep venous thrombosis in the left arm. She was started on a blood thinner (eliquis). She had blood tests done on 1/1/20 and this showed leukocytosis. She was found to have acute myeloid leukemia and admitted to our service for treatment. We do not have blood tests prior to 1/1/20 so it is unclear when her leukemia started. Her deep venous thrombosis could be related to her acute leukemia but I decided to report it due to the proximity to the time of her vaccine. Her arm pain and swelling improved after administration of the blood thinner. She is currently being treated for her leukemia.
COVID19 VACCINE	PFIZER\BIONTECH	0938576-1	18-29 years	3 days	Back pain, bilateral PE and DVT

COVID19 VACCINE	PFIZER\BIONTECH	0944289-1	18-29 years	3 days	she was diagnosed with bilateral deep vein thrombosis (DVT) and pulmonary embolism (PE); she was diagnosed with bilateral deep vein thrombosis (DVT) and pulmonary embolism (PE); This is a spontaneous report from a contactable nurse (patient). A 22-year-old female patient received 2nd dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EK9231), via an unspecified route of administration in left arm on 06Jan2021 13:45 at single dose for COVID-19 immunisation. Medical history included allergy to all fish, and clots. The patient was not pregnant. There were no concomitant medications. The patient previously received 1st dose of BNT162B2 (lot numer: EH9899) in left arm on 16Dec2020 13:45 for COVID-19 immunisation and experienced left sided lower back pain on 20Dec2020. No other vaccine received in four weeks. It was reported that the patient had the first covid vaccine on 16Dec2020 and on 20Dec2020 started with left sided lower back pain and then received the second on 06Jan2021 and then on 09Jan2021 11:00 her legs became blue and swollen and she was diagnosed with bilateral deep vein thrombosis (DVT) and pulmonary embolism (PE). The patient otherwise healthy and had never had covid. Other than the clots, she had no other health issues. The patient underwent lab tests and procedures which included nasal swab: negative on 09Jan2021. Events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, and life threatening illness (immediate risk of death from the event), hospitalized for 2 days (in Jan2021). Adverse event treatment: heparin drip and xarelto at home. Recovered with lasting effects on an unspecified date of Jan2020. This case was reported as serious, serious criteria was life threatening, caused/prolonged hospitalization.; Sender's Comments: The underlying risk factors/predisposing condition of thrombotic diathesis have been assessed to have played a contributory role toward the events.
COVID19 VACCINE	PFIZER\BIONTECH	0959469-1	30-39 years	3 days	Employee received her 2nd Pfizer vaccine on 1/12/2021. Twelve hours later she developed a fever with a T-max of 102 degrees. The fever lasted 18 hours. She also complained of severe malaise and fatigue lasting 36 hours. On day 3 she developed left lower extremity pain that persisted over the weekend. She was seen in Urgent Care today where she was diagnosed with a thrombosis. She also came to the ETC and was ruled out for a PE The employee does have a family history of antiphospholipid in her mother. She has a follow up with her PCP and will also receive a work up in hematology as she had never been tested for any genetic coagulation conditions after her mom's diagnosis.
COVID19 VACCINE	PFIZER\BIONTECH	0959492-1	30-39 years	3 days	Employee received her 2nd Pfizer vaccine on 1/12/2021. Twelve hours after her vaccine she developed a fever with a T-max of 102 degrees. The fever lasted 18 hours. She also complained of severe malaise and fatigue lasting 36 hours. On day 3 (Friday, January 15, 2021) she developed left lower extremity pain that persisted over the weekend. She was seen in Urgent Care today where she was diagnosed with a deep vein thrombosis of the proximal vein. She also came to the ETC and was ruled out for a PE. The employee does have a family history of antiphospholipid in her mother. She has a follow up with her PCP and will also receive a work up in hematology as she had never been tested for any genetic coagulation conditions after her mom's diagnosis.
COVID19 VACCINE	PFIZER\BIONTECH	0974464-1	30-39 years	3 days	PRESENTING PROBLEM: Bilateral pulmonary embolism (HCC) HOSPITAL COURSE: 35-year-old female came in with shortness of breath and pleuritic chest pain who was found to have bilateral pulmonary embolism with moderately extensive clot burden. Her BNP and troponins were normal and no signs of right ventricular dysfunction on CT scan. Patient was placed on heparin drip and her symptoms improved. Ultrasound Doppler of bilateral lower extremities were negative. This was an unprovoked PE. Patient was switched to and discharged with Xarelto. She will benefit from a hypercoagulable workup once she is off of anticoagulation. After vaccine: patient reported difficulty breathing and fast heartrate

COVID19 VACCINE	PFIZER\BIONTECH	0988076-1	50-59 years	3 days	<p>On day 04 After receiving the 2nd Covid 19 Pfizer vaccine, I experienced a deep pain in my upper inner right thigh around 0600 am of the 16th of January. At the same time my calf muscle of that same right leg was in pain. I thought it to be muscular pain as I was told by the reading material regarding symptoms of the covid 19 vaccine there could be aches an pains attributed to the 2nd shot. I used a deep heating rub on both areas of my right leg and put heat on them to treat the soreness. This ocured over the next few days feeling this pain in my right leg and treated the same way applying heat. Within about 24 hours of the pain in my legs I started experiencing a shortness of breath while walking up and down st. On day 04 After receiving the 2nd Covid 19 Pfizer vaccine, I experienced a deep pain in my upper inner right thigh around 0600 am of the 16th of January. At the same time my calf muscle of that same right leg was in pain. I thought it to be muscular pain as I was told by the reading material regarding symptoms of the covid 19 vaccine there could be aches an pains attributed to the 2nd shot. I used a deep heating rub on both areas of my right leg and put heat on them to treat the soreness. This ocured over the next few days feeling this pain in my right leg and treated the same way applying heat. Within about 24 hours of the pain in my legs I started experiencing a shortness of breath while walking up and down stairs as part of my daily activities. The symptoms of shortness of breath only seemed to appear when I was on any form of extended walking activity or physical movements or exercise this would of have been starting around the 17th of January. The right leg pain was masked by the heating rub while the shortness of breath continued for the next few days. On the 19th of January, I went to an Urgent Care Facility at 0800 am to see a Medical professional to discuss my symptoms I was previously experiencing and to figure out why I was having a shortness of breath and the pain in my right leg. The on staff Physician's Assistant had a Nurse conduct a Covid 19 Rapids test (negative) and a second swab was administered and sent to the Lab. Which produced a (negative for Covid 19) on the 20th of January. An Xray was not taken to determine my shortness of breath. The Dr listened to my lungs and heart, though I did let the PA know I had received both Pfizer shots and when they were administered. I was carrying My Shot record for the vaccine with the dates and lot number. He didnt appear to be interested in further diagnosis and made sure I had the paperwork to track the results of my Covid swab sent to the lab. The visit was completed and I was released to go back to work/home. I carried on the symptoms of the shortness of breath from the 19th of January to the 22nd of January monitoring my O2 (oxygen levels) with a pulse oximeter. They ranged from 90-93. On the evening of the 22nd of January I was becoming very uncomfortable with my breathing climbing the stairs in my home and monitored my O2 readings with the oximeter on my finger when walking upstairs and they dropped down to 60-65. My wife drove me to the emergency room at Hospital. I walked into the ER and checked myself in for shortness of breath and leg pain in my right leg. I was admitted into the emergency room and put on 15 litres of oxygen. The emergency room Dr ordered a chest Xray, Cat Scan of my chest and heart and a sonogram of my right leg. The testing results came back with a noted large pulmonary emboli on my lungs/heart area and blood clots throughout my right leg (right lower extremity DVT). Surgery was performed to remove the pulmonary emboli and I</p>
COVID19 VACCINE	PFIZER\BIONTECH	0992810-1	65+ years	3 days	<p>Concern comes from a pulmonary Embolism and DVT diagnosed within a week of the first shot. Realize this could be a coincidence, I have no history of clots.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1011807-1	65+ years	3 days	<p>general malaise , Fatigue, poor interest in activities , hypoactivity, pulmonary embolism Narrative: Patient transferred to ER for evaluation. Physician at facility reported marked deterioration, hypoactivity and slow mentation s/p COVID vaccine second dose 1/8/21. Cough also reported x 1 week. Patient evaluated at ER on 1/20/21 and admitted to internal medicine ward with diagnosis impression pulmonary emboli, aspiration pneumonia and urinary tract infection.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1015212-1	18-29 years	3 days	<p>Deep Venous Thrombosis of Right Axillary and Subclavian vein. Treated with IV Heparin Drip.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1023638-1	50-59 years	3 days	<p>Dose #2 - Nose bleeds following the 2nd Pfizer COVID-19 vaccine beginning a few days later and lasting at least (1) one week; on 2/2/2021 this patient coughed up a pea-sized bright red blood clot; no blood clots noted since that one time and no petechiae noted; severe body and joint aches and pain beginning the next day and lasting 24 hours. No fever noted on any day. Dose #1 - Nausea / diarrhea beginning a few days later and lasting two and one-half (2 1/2) weeks; sore arm same day and lasting at least 3 days. No fever noted on any day.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1025489-1	65+ years	3 days	Patient received 1st dose of vaccine on 2/6/21. That afternoon, developed malaise and fever/chills over the next few days. On the evening on 2/9/21, began to have left-sided chest pain (severe, pleuritic, radiating to left arm) leading her to seek medical care. Was determined to have viral pericarditis and admitted to the hospital for several days
COVID19 VACCINE	PFIZER\BIONTECH	1044569-1	65+ years	3 days	THROMBOTIC STROKE IN THE DISTRIBUTION OF THE LEFT MCA DISTRIBUTION
COVID19 VACCINE	PFIZER\BIONTECH	1046600-1	65+ years	3 days	Patient was admitted and treated for severe PE and DVT, as well as hypoxia and paroxysmal SVT. Pt was discharged to inpatient rehab when stable
COVID19 VACCINE	PFIZER\BIONTECH	1061209-1	65+ years	3 days	Sharp pain behind right knee. Subsided by evening. Went to The ER Sunday morning, Feb. 21. They x-rayed leg and found nothing unusual for a woman my age. Then they conducted a scan and discovered a blood clot behind my knee. Since then, I have had intermittent pain. The Doctor referred me to a hematologist which I will see this week. Prior to the vaccination have never had a blood clot. It occurred three days after the vaccination. Coincidence? I think not.
COVID19 VACCINE	PFIZER\BIONTECH	1064214-1	65+ years	3 days	Pulmonary Embolism suffered on 2/13/2021. Hospitalized at Medical Center. Discharged on 2/20/2021. Still recovering.
COVID19 VACCINE	PFIZER\BIONTECH	1073679-1	18-29 years	3 days	Pulmonary embolisms; lung infarcts in left and right lungs; This is a spontaneous report from a contactable consumer (patient). A 28-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL5269), via an unspecified route of administration at site of left arm at 15:00 on 08Feb2021 at single dose for COVID-19 immunisation. Medical history included psoriasis and known allergies: clarithromycin. The patient's concomitant medications were not reported. The patient previously took the first dose of BNT162B2 on an unspecified date. The patient experienced pulmonary embolisms and lung infarcts in left and right lungs on 11Feb2021. The patient was hospitalized for these events for 2 days. COVID was tested post vaccination (Nasal Swab covid test with negative result on 12Feb2021). No other vaccine received in four weeks. Adverse events resulted in Doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event). The patient received treatment (blood thinners and CT Imaging) for adverse event. No COVID prior vaccination. The outcome of events was recovered in Feb2021.
COVID19 VACCINE	PFIZER\BIONTECH	1079045-1	65+ years	3 days	Initially, a UTI developed. As the UTI resolved, double pneumonia took hold. At the hospital they then discovered multiple clots in the legs.
COVID19 VACCINE	PFIZER\BIONTECH	1086429-1	65+ years	3 days	Patient developed left sided pleuritic chest pain and dyspnea on 3/8 in the evening. She presented to the ED 3/9 and was found to have a segmental left lower lobe pulmonary embolism (left lateral basilar segment) with associated LLL pulmonary infarction. She had tachycardia to low 110s, mild hypoxia to 89% on room air with no evidence of pneumonia or typical COVID infiltrates. She had no known COVID exposure. She had one prior pulmonary embolism in 1999 treated for 6 months with coumadin, and was subsequently found in 2000 to be heterozygous for Factor V Leiden. She is being admitted to the hospital for treatment of pulmonary embolism.
COVID19 VACCINE	PFIZER\BIONTECH	1101216-1	65+ years	3 days	DVT's in both legs
COVID19 VACCINE	PFIZER\BIONTECH	1102279-1	65+ years	3 days	Diagnosis of a deep vein thrombosis in the left leg.
COVID19 VACCINE	PFIZER\BIONTECH	1102813-1	65+ years	3 days	Developed an Acute nonocclusive DVT in left leg 10 days after my first vaccine. Decided to decline my second vaccine. I do have a history of having blood clots, but last one was 32 years ago.
COVID19 VACCINE	PFIZER\BIONTECH	1104607-1	65+ years	3 days	Stroke on 2/11/2021 caused by a blot clot
COVID19 VACCINE	PFIZER\BIONTECH	1105661-1	60-64 years	3 days	Blood Clot's small in distal region of lungs bilateral 3 days after injection of vaccine
COVID19 VACCINE	PFIZER\BIONTECH	1109297-1	65+ years	3 days	Patient has a progressive dry cough and dyspnea on exertion that started a few days after receiving the second dose of the COVID vaccine. He received a 10 day course of doxycycline for CAP as an outpatient without any improvement, hence he was admitted to the hospital for further workup. CT scan was performed revealing findings concerning for ILD. Of note a CT done in 2018 shows some possible early signs of ILD. Pulmonology is seeing the patient and he was started on steroids today (3/17/2021).
COVID19 VACCINE	PFIZER\BIONTECH	1127873-1	40-49 years	3 days	Pulmonary Emboli, shortness of breath

COVID19 VACCINE	PFIZER\BIONTECH	1129443-1	40-49 years	3 days	The patient is a 41 yo male with a history of seasonal allergic rhinitis who experienced DVT and PE temporally related to Pfizer BioNTech COVID vaccine dose #2 receipt. He is a Service Member and reported high levels of baseline activity, including running 10 miles each Saturday. He received vaccine #1 25 JAN 21 (EN5318) without AE. He received dose #2 on 16 FEB 21, (EN6200). He experienced no immediate symptoms suggestive of IgE event. On day 1 he reports feeling cold, mild fatigue but no other symptoms. On day 2 he was baseline. On day 3 he noted numbness, tightness and discomfort to his right calf. On day 4 (Saturday), his usual long run day, he experienced dyspnea and lightheadedness after running 20-30 feet. He states he noted tightness in his calf and instead walked the track while his wife completed her run. He rested day 5. Day 6 he noted significant edema to his calf, which he describes as double normal in size, and iced it. Day 7, he tried to schedule with PCP and based on triage was sent to ER. ER diagnosed R DVT and bilateral PE's. He was admitted overnight, started anticoagulation therapy. He saw hematology, and the workup was negative for other causes.
COVID19 VACCINE	PFIZER\BIONTECH	1137230-1	60-64 years	3 days	3 days after completing vaccine series, pt develop right leg pain and swelling, which progressed later on to shortness of breath after a week.
COVID19 VACCINE	PFIZER\BIONTECH	1139491-1	40-49 years	3 days	I had my second vaccine on Monday, 3/22, and woke up at 1am on Thursday 3/25 with extreme chest pain, shortness of breath, sweating and chills. I went to the ER, and they discovered two blood clots in my lungs. I've never had pulmonary embolisms before, so this is a very strange coincidence. I am in cancer treatment, so my risk of PEs is higher, but the timing is too close for me not to think that the second vaccine traumatized my immune system, causing the PEs.
COVID19 VACCINE	PFIZER\BIONTECH	1148782-1	30-39 years	3 days	Pain in left calf leading to development of blood clot above left knee cap near inside of quad; Pain in left calf leading to development of blood clot above left knee cap near inside of quad; This is a spontaneous report from a contactable consumer. A 38-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration, administered in Arm Left on 01Mar2021 12:00 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. Medical history included U/L fasciotomy in same leg with nerve damage, Blood transfusion, previous clot in femoral during recovery, Shellfish (allergy). The patient has not had COVID prior vaccination. The patient received first dose of BNT162B2 for COVID-19 immunization on an unspecified date (lot number: unknown) at 38-years-old. Concomitant medication included sulfamethoxazole, trimethoprim (BACTRIM) taken for an unspecified indication, start and stop date were not reported. On 04Mar2021 16:00, the patient experienced Pain in left calf leading to development of blood clot above left kneecap near inside of quad. AE resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The patient received treatment for the events: Originally treated as cellulitis with doxy. The outcome of the events was recovering. The patient was not tested for COVID post vaccination. Information about Lot/Batch number is requested.
COVID19 VACCINE	PFIZER\BIONTECH	1150385-1	65+ years	3 days	I had a return of a superficial thrombophlebitis on my left arm above where a catheter had been when I had surgery 7 weeks before. The blood clot returned again to the same level of pain and the same; I had a return of a superficial thrombophlebitis on my left arm above where a catheter had been when I had surgery 7 weeks before. The blood clot returned again to the same level of pain and the same; This is a spontaneous report from a contactable consumer (patient). A 67-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in right arm on 01Mar2021 13:30 (lot/batch number was not reported) as single dose for COVID-19 immunisation. The patient's medical history included high blood pressure. The patient had no known allergies. The patient's concomitant medications were not reported. On 04Mar2021 07:30, the patient had a return of a superficial thrombophlebitis on her left arm above where a catheter had been when she had surgery 7 weeks before. The blood clot returned again to the same level of pain and the same. No treatment was received for the events. Patient was not pregnant at the time of vaccination. Patient had no COVID prior to vaccination and not tested for COVID post vaccination. Vaccine facility type was other. There was no other vaccine in four weeks and there was other medications in two weeks. The outcome of the events were not recovered. Information on the lot/batch number has been requested.

COVID19 VACCINE	PFIZER\BIONTECH	1151450-1	60-64 years	3 days	Deep Vein Thrombosis/he have numbness , tingling on his left foot. It was also swollen; CT scan shows he have PE; This is a spontaneous report from a contactable consumer (patient) reported that a 61-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in arm left on 24Feb2021 10:15 as a single dose (at the age of 61-years-old) for covid-19 immunisation. The vaccine was administered at the hospital. Medical history included back pains, acid reflux and chest pain; all from an unknown date. Concomitant medication included esomeprazole sodium (NEXIUM [ESOMEPRAZOLE SODIUM]) taken for an unspecified indication, start and stop date were not reported. The patient reported that after several days of getting his first shot, he have numbness , tingling on his left foot. It was also swollen, he went to the Emergency and they found out he have deep vein thrombosis and CT scan shows he have PE on 27Feb2021. The reported events resulted in emergency room/department or urgent care. The patient received treatment for the events which was a blood thinner, Eliquis. The outcome of the events was not recovered. Information on the lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1159775-1	65+ years	3 days	3/6/21-About two in a half days following the 2nd dose, patient had sudden onset of right sided chest pain, pleuritic, lasted several days- did not seek attention. 3/17/21- Sudden onset of severe left sided pleuritic chest pain and dyspnea. Presented to ER, found to have extensive Bilateral Pulmonary Emboli. 3/17/21- Patient admitted to Hospital. Initially put on anticoagulation, but due to GI bleeding had placement of Inferior Vena Cava Filter. 3/23/21- Discharged from Hospital.
COVID19 VACCINE	PFIZER\BIONTECH	1162481-1	65+ years	3 days	Two blood clots in my right calf that travelled up to my lungs; Shortness of breath; Pain in my right calf; Had difficulty just walking; This is a spontaneous report from a contactable consumer (patient). A 73-years-old non pregnant female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration in left arm on 12Feb2021 19:30 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. Medical history included heart (as reported) and known allergies to penicillin. There concomitant medications were not reported. On 15Feb2021 18:30 the patient experienced two blood clots in my right calf that travelled up to my lungs, shortness of breath, pain in my right calf, had difficulty just walking. It was reported that two nights after receiving the vaccine, she suffered shortness of breath and pain in her right calf. She tried to relax the next day, but had difficulty just walking. She went to a walk in medical facility. They sent her to the ER. After testing they found that she had two blood clots in her right calf that travelled up to my lungs. The event two blood clots in my right calf that travelled up to my lungs was considered as serious (hospitalization) and other event were considered as serious (hospitalization). The patient was hospitalized for all events for 4 days. The patient underwent lab tests and procedures which included blood test on 15Feb2021 with showed two blood clots in my right calf that travelled up to my lungs and sars-cov-2 test with negative results on Feb2021. Therapeutic measures were taken as a result of two blood clots in my right calf that travelled up to my lungs, shortness of breath, pain in my right calf and had difficulty just walking. AE treatment included blood thinner. The outcome of the events was recovering. No other vaccine was given to patient in four weeks and two weeks. No Covid prior vaccination. If Covid tested post vaccination: Yes. Patient was covid tested post vaccination in Feb2021 with negative results. AE resulted in: [Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization]. Facility type vaccine was Public Health Clinic facility. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected
COVID19 VACCINE	PFIZER\BIONTECH	1166312-1	40-49 years	3 days	patient developed malaise, abdominal pain and nausea 2 days after the vaccination. It did not improve for a week and he presented to the hospital and was diagnosed with acute superior mesenteric vein and portal vein thrombosis along with pancreatic edema
COVID19 VACCINE	PFIZER\BIONTECH	1173347-1	65+ years	3 days	Right lower extremity deep venous thrombosis.

COVID19 VACCINE	PFIZER\BIONTECH	1191825-1	65+ years	3 days	DVT L leg, possible PE; DVT L leg, possible PE; This is a spontaneous report from a contactable physician. A 76-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date were not reported), via an unspecified route of administration on 09Mar2021 (at the age of 76 years old) at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient previously took NSAIDs. The patient experienced DVT L leg, possible PE on 12Mar2021. Treatment given included Eliquis. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19. The outcome of the events was recovering. Information on the batch/lot number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported events deep vein thrombosis and possible pulmonary embolism occurred in a plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1204321-1	40-49 years	3 days	DVT right leg began on evening of Feb 28 but became evident March 1 morning and diagnosed evening at ER
COVID19 VACCINE	PFIZER\BIONTECH	1205201-1	40-49 years	3 days	Three days after receiving the vaccine, I developed a blood clot in the lining of my stomach.; This is a spontaneous report from a contactable consumer. A 42-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; Batch/Lot Number: EN6201), dose 1 via an unspecified route of administration, administered in Arm Left on 15Mar2021 11:30 as SINGLE DOSE for covid-19 immunization. The patient medical history was not reported. Concomitant medication(s) included ethinylestradiol, norgestimate (SPRINTEC) taken for an unspecified indication, on an unspecified date. On 18Mar2021 05:30 the patient experienced three days after receiving the vaccine, developed a blood clot in the lining of her stomach (thrombosis). The patient was hospitalized for three days after receiving the vaccine, developed a blood clot in the lining of her stomach for 3 days. Therapeutic measures with blood thinners were taken as a result of three days after receiving the vaccine, developed a blood clot in the lining of her stomach. The outcome of the event was recovered. Information on Lot/Batch number was available. Additional information has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1206421-1	6-17 years	3 days	Blood clot in right calf. Noticed pain and knot in calf on Sunday 3/14/2021. It worsened over the next few days. Went to Urgent care on 3/18 and they sent us straight to ER for Ultrasound. In hospital they found it was a clot identified as deep vein thrombosis, and started a treatment of blood thinner and pain medication.
COVID19 VACCINE	PFIZER\BIONTECH	1208319-1	50-59 years	3 days	The patient is a 50 year old female with no medical problems who developed sudden severe headache on 3/24 accompanied by nausea and vomiting. She presented to urgent care on 3/25 and was considered to be dehydrated and given IV fluids. On 3/27 she developed left hand weakness. On 3/29 she revisited urgent care with residual symptoms plus hand weakness and was sent to hospital where she was admitted and MRV demonstrated Cerebral Venous Sinus Thrombosis of the sagittal sinus, right transverse sinus, and right sigmoid sinus. The left transverse sinus may also be occluded or congenitally absent. There was no evidence of hemorrhage or stroke. The patient was admitted and started on heparin then transitioned to Eliquis and discharged. On 4/3, she had worsening of symptoms consisting of dysarthria, left facial, and worse left arm and hand weakness. She was readmitted to hospital then transferred to hospital for further management.
COVID19 VACCINE	PFIZER\BIONTECH	1213311-1	65+ years	3 days	Pt was diagnosed with cerebral venous sinus thrombosis on 3/25/21 after having severe HA x 3 days. Looking back, she had a cbc for other reasons on 2/24/21 (3 days after her 2nd Covid vaccine) that showed a drop in platelets to 126,000 (although platelets in 2020 were 150,000)
COVID19 VACCINE	PFIZER\BIONTECH	1215159-1	30-39 years	3 days	acute SMV/IMV/portals vein thrombus
COVID19 VACCINE	PFIZER\BIONTECH	1219841-1	30-39 years	3 days	50 hours after receiving vax shortness of breath and found blood clotting in lungs and legs

COVID19 VACCINE	PFIZER\BIONTECH	1227231-1	18-29 years	3 days	cerebral venous sinus thrombosis; CT scan that revealed the dot; horrible headache after intercourse; vomiting; This is a spontaneous report from a contactable consumer (patient). A 29-years-old non-pregnant female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/Lot Number: EP7534), second dose via an unspecified route of administration, administered in left arm on 25Mar2021 09:45 as single dose for COVID-19 immunisation. Patient was 29 year old at the time of vaccination. Medical history included asthma, gastroesophageal reflux disease, peanut and tree nut allergy, all from an unknown date. Patient had estrogen allergy. Patient was not diagnosed with COVID-19 Prior to or after the vaccination. Concomitant medications included cetirizine hydrochloride (ZYRTEC ALLERGY), medroxyprogesterone acetate (DEPO PROGESTIN), beclometasone dipropionate (QVAR), OMEPRAZOLE, SERTRALINE HYDROCHLORIDE, all taken on an unspecified date and for unknown indication. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient had her first dose of bnt162b2 on 04Mar20210 at 9:45 am in left arm for COVID-19 immunisation. On 28Mar2021 at 09:45 the patient was diagnosed with cerebral venous sinus thrombosis a few days after receiving the second dose of the vaccine. She had a horrible headache after intercourse, went to the ER after vomiting, and had a CT scan that revealed the dot. The patient was hospitalized for cerebral venous sinus thrombosis. The patient underwent lab tests and procedures which included computerised tomogram: revealed the dot. Patient received Heparin and Eliquis as treatment for the events. Outcome of the events was recovering. No follow-up attempts needed. No further information expected.
COVID19 VACCINE	PFIZER\BIONTECH	1227959-1	40-49 years	3 days	Multiple pulmonary embolism in both lungs; This is a spontaneous report from a contactable consumer (patient). A 46-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in left arm on 25Feb2021 10:00 (Batch/Lot Number: Ew6202) as single dose, for covid-19 immunisation at a pharmacy/drug store. Medical history included diabetes. The patient has no known allergies and no COVID prior to vaccination. The patient has other medications in two weeks but no other vaccine in four weeks. The patient experienced multiple pulmonary embolism in both lungs on 28Feb2021 08:00. The patient was hospitalized for multiple pulmonary embolism in both lungs for 3 days. The event resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care visit, and considered life threatening illness (immediate risk of death from the event). The patient was treated with blood thinners. The patient had the second dose of BNT162B2 on 18Mar2021 at 11:00 am in the left arm. The patient was tested for Covid post vaccination via nasal swab (rapid) on 10Apr2021 which was negative. The outcome of the event was not recovered.
COVID19 VACCINE	PFIZER\BIONTECH	1235790-1	50-59 years	3 days	pulmonary embolism; shortness of breath; This is a spontaneous report from a contactable consumer (patient). A 50-year-old male patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot ep7534), via an unspecified route of administration, administered in right arm on 16Mar2021 15:00 as single dose for covid-19 immunisation. Medical history included high blood pressure. Concomitant medication included verapamil. The patient previously took lisinopril and experienced allergies. The patient received first dose of bnt162b2 on 23Feb2021, 13:00 for Covid-19 immunization. On 19Mar2021, the patient started having challenges with shortness of breath. On 31Mar2021, after the challenge continued to grow he was checked into the hospital and was diagnosed with pulmonary embolism. Despite no travel nor history of family blood clots, nor was he was genetically dispositioned. The events resulted in emergency room/department or urgent care. Therapy for the events included Blood thinner. The patient had no other vaccine in 4 weeks, and no Covid prior vaccination. The patient was Covid tested post vaccination. The patient underwent lab tests and procedures which included nasal swab was negative on 31Mar2021. Outcome of events was recovering.

COVID19 VACCINE	PFIZER\BIONTECH	1235813-1	40-49 years	3 days	Main portal vein, right portal vein, and SMV thrombus; This is a spontaneous report from a contactable consumer (patient). The 45-years-old male patient received bnt162b2, dose 2 via an unspecified route of administration, administered in Arm Left on 26Mar2021 07:15 (Batch/Lot Number: EP6955) as SINGLE DOSE for covid-19 immunization. The patient medical history was not reported. No known allergies. There were no concomitant medications. The patient previously received first dose of bnt162b2 on 05Mar2021 07:00 AM (lot number=EN62020) in right arm at single dose for Covid-19 immunization. No other vaccine in four weeks and Other medications in two weeks. No Covid prior vaccination. The patient experienced main portal vein, right portal vein, and smv thrombus on 29Mar2021 04:00. The patient was hospitalized for the event for 4 days. The AE resulted in Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event). The patient underwent Covid tested post vaccination via Nasal Swab for SARS-CoV-2 on 03Apr2021 and was negative. The patient was treated with heparin, currently on Xarelto. The outcome of the event was recovered with sequelae No follow-up attempts are possible. No further information is expected.
COVID19 VACCINE	PFIZER\BIONTECH	1235838-1	50-59 years	3 days	Extreme inflammatory response. In ER/hospitalized 5 days post vaccine; Had Angiogram, found clot in Obtuse Marginal; This is a spontaneous report from a contactable consumer (patient). A 54-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 21Mar2021 12:00 (Lot Number: EN6207), age at vaccination of 54-years-old, as single dose for covid-19 immunisation. Medical history included cardiac failure from an unknown date and unknown if ongoing, connective tissue disorder from an unknown date and unknown if ongoing. Patient was not pregnant. Concomitant medications included hydroxychloroquine sulfate (PLAQUENIL [HYDROXYCHLOROQUINE SULFATE]) taken for an unspecified indication, start and stop date were not reported; isosorbide mononitrate (IMDUR) taken for an unspecified indication, start and stop date were not reported; metoprolol (METOPROLOL) taken for an unspecified indication, start and stop date were not reported; rosuvastatin calcium (CRESTOR) taken for an unspecified indication, start and stop date were not reported; furosemide (FUROSEMIDE) taken for an unspecified indication, start and stop date were not reported. The patient previously took codeine and experienced hypersensitivity. The patient experienced extreme inflammatory reaction on 24Mar2021 at 04:00 AM and clot blood on 24Mar2021; events were serious as resulted in Emergency room/department or urgent care, hospitalization (for 5 days), life threatening illness (immediate risk of death from the event). The patient had extreme inflammatory response; in ER/hospitalized 5 days post vaccine. Angiogram was performed and clot in obtuse marginal was found; unable to remove clot, surgeon was able to break it apart and balloon the vessel open. It was unknown if patient had COVID prior vaccination. Patient had no other vaccine in four weeks. Sars-cov-2 test was negative on 15Apr2021. The patient was considered to be recovering from the events.
COVID19 VACCINE	PFIZER\BIONTECH	1261824-1	50-59 years	3 days	swelling in her right foot and right calf and pain/blood clot was diagnosed in her right calf under her knee; This is a spontaneous report from a contactable consumer (patient). A 52-year-old female patient received the second dose of bnt162b2, via an unspecified route of administration, administered in left arm on 31Mar2021 (Lot Number: ER8732) as single dose for covid-19 immunisation. There were no medical history and concomitant medications. The patient previously received the first dose of bnt162b2, at the age of 52-year-old, via an unspecified route of administration, administered in left arm on 10Mar2021 11:15(Lot Number: EN6206) as single dose for covid-19 immunization. Started experiencing swelling in her right foot and right calf and pain 3 days following 2nd injection (03Apr2021). Went to the doctor and blood clot was diagnosed in her right calf under my knee 9 days following 2nd injection (09Apr2021). Event resulted in Doctor or other healthcare professional office/clinic visit, Life threatening illness (immediate risk of death from the event). The treatment for event was 21 Days Xarelto BID then Pradaxa for 90 days. The patient was not pregnant. The outcome of the event was recovering.

COVID19 VACCINE	PFIZER\BIONTECH	1269520-1	65+ years	3 days	blood clots in urine for 36 hours commencing about three days after second shot; This is a spontaneous report from a contactable consumer, the patient. A 78-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN) via an unspecified route of administration, administered in the right arm on 11Mar2021 (at the age of 78-years-old) as a single dose for COVID-19 immunisation. Medical history included arrhythmia from an unknown date and unknown if ongoing, and sulfa allergy from an unknown date and unknown if ongoing. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. Concomitant medication included apixaban (ELIQUIS) for an unspecified indication, start and stop date were not reported. The patient had not received any other vaccines within 4 weeks prior to the COVID-19 vaccine. The patient previously received the first dose of BNT162b2 on 18Feb2021 (Lot Number: Unknown) in the right arm for COVID-19 immunisation. On 14Mar2021, the patient experienced blood clots in urine for 36 hours commencing about three days after second shot. No treatment given for the event. The patient with outcome of recovered from the event, blood clots in urine for 36 hours on an unknown date in Mar2021. Information on the lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1278671-1	65+ years	3 days	Blood clots in lungs and UTI; Blood clots in lungs and UTI; This is a spontaneous report from a contactable consumer. A 68-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 28Mar2021 (Batch/Lot number was not reported) as SINGLE DOSE (at the age of 68 years) for covid-19 immunisation. Medical history was none. Known allergies was none. The patient did not have Covid prior to vaccination. No other vaccine was given in last four weeks. There were no concomitant medications. The patient experienced blood clots in lungs on 31Mar2021 with outcome of recovering and UTI (urinary tract infection) on 31Mar2021 with outcome of recovering. Adverse event blood clots in lungs and UTI resulted in Emergency room/ department or urgent care and then hospitalization for 6 days. The patient underwent lab tests and procedures which included sars-cov-2 antibody test: negative on 11Apr2021. Therapeutic measures were taken as a result of blood clots in lungs and UTI and included blood thinner. Information about lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1281533-1	65+ years	3 days	Blood clot in the lungs, Death
COVID19 VACCINE	PFIZER\BIONTECH	1284864-1	65+ years	3 days	blood clot in her leg; blood clot in her leg; Cardiac arrest; Heart attack; This is a spontaneous report from a contactable consumer (patient's daughter). A 96-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 2 via an unspecified route of administration on 29Jan2021 (Lot Number: EL9265) as SINGLE DOSE for COVID-19 immunization. Medical history included blood clots in her legs from an unknown date and unknown if ongoing, diabetec, bone infection, surgery and anemic; all from an unknown date and unknown if ongoing; and a family history of gangrene from an unknown date and unknown if ongoing of her mother. Concomitant medications included apixaban (ELIQUIS) taken as blood thinner and furosemide (FUROSEMIDE) taken for an unspecified indication; both start and stop date were not reported. The patient previously had BNT162B2 (Lot Number: EL1283) dose 1 on 08Jan2021 for COVID-19 immunization. The facility where the most recent COVID-19 vaccine was administered was in the military facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. On 15Mar2021, the patient died due to a heart attack and cardiac arrest. The patient developed a blood clot in her leg and had to have her leg taken off. The date of surgery was 05Feb2021, not early Mar2021 like was originally stated at the hospital. The patient was admitted either on 01Feb2021 or 02Feb2021 and discharged on 23Feb2021. They had a bunch of bad weather and then they put the patient in the nursing facility for about a month and when she was brought home she had a heart attack and died due to cardiac arrest. She doesn't know about the blood clot and this being related to the COVID vaccines but the patient had surgery a week after she had her second shot. The heart attack was on 15Mar2021. The patient had a history of blood clots in her legs before and she had problems with that so that might of made it worse but she doesn't know for sure. The patient died on 15Mar2021. An autopsy was not performed. The outcome of the event blood clot in her leg was unknown. No follow-up attempts are possible; information about lot/batch number has been obtained.; Reported Cause(s) of Death: heart attack; cardiac arrest

COVID19 VACCINE	PFIZER\BIONTECH	1294665-1	Unknown	3 days	three smallest toes on both feet (left/right) feel swollen; discomfort in wearing shoes and sleeping at night; balance is affected; nerve damage; discoloration; blood clots; This is a spontaneous report from a contactable consumer (patient). A 57-years-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiry date: unknown), via an unspecified route of administration, administered in Arm Left on 06Mar2021 11:00 as single dose for COVID-19 immunization. The patient had no medical history and known allergies. Patient did not have COVID prior vaccination. Patient was not tested for COVID post vaccination. Concomitant medications were not reported. It was reported that patient had three smallest toes on both feet (left/right) feel swollen. He had discomfort in wearing shoes and sleeping at night. He had movement of the toes but balance is affected. Just really troubling as nothing like this was affecting him before. He had been told it was COVID toe. He first thought it is was nerve damage. Could be blood clots small based on reading information. He never got sick. He was attempting to set a doctors appointment. There is a small amount of discoloration. He was hopeful with time this will get better. Events started on 09Mar2021 14:00 with outcome of not recovered. No treatment received. Events resulted in Doctor or other healthcare professional office/clinic visit, Disability or permanent damage. Events were reported as serious due to disability. Patient had second dose of bnt162b2 (lot no.: ER2613) on 27Mar2021 on Left Arm. Information on the lot/batch number has been requested.
COVID19 VACCINE	UNKNOWN MANUFACTURER	1209444-1	40-49 years	3 days	Blood clots in my lungs
COVID19 VACCINE	JANSSEN	1125625-1	65+ years	4 days	3/11/21- pt was feeling fine. She stood up got dizzy and seemed to have a seizure. when she came to she did not know that it had happened. about 5 hours later she stood up again got dizzy and seemed to have had another seizure. her husband called 911. EMTs took her vitals but did not detect anything to be wrong at the time and was advised to see PCP. Next day 3/12/21 she went to her PCP. She had blood work which showed high enzymes for heart failure so was sent to hospital to be admitted. Pt had blood work, chest xray which showed blood clots in both lungs. She was administered blood thinner. MRI of head was clear. Echocardiogram was clear. Pt stayed about 4 days. Enzymes for heart failure was clearing up. Pt was released and had a FU appt w/ PCP on 3/22/21. Pt found out that she also had bilateral deep vein thrombosis in both legs while she was in the hospital. Pt is improving and is almost back to normal.
COVID19 VACCINE	JANSSEN	1132787-1	30-39 years	4 days	Within a week of getting the vaccine I developed a blood clot in the lining of my stomach
COVID19 VACCINE	JANSSEN	1169918-1	65+ years	4 days	She developed symptoms of right lower leg pain 4 days after receiving the vaccine. It then progressed to right chest pain, tachycardia, and shortness of breath. She was diagnosed with a DVT and PE.
COVID19 VACCINE	JANSSEN	1190483-1	60-64 years	4 days	4 days after vaccinated I had massive pulmonary embolism in both lungs.
COVID19 VACCINE	JANSSEN	1192913-1	18-29 years	4 days	Left greater saphenous vein superficial thrombophlebitis
COVID19 VACCINE	JANSSEN	1200876-1	40-49 years	4 days	My mother received the Jansen vaccination on April 6, 2021. 2 days post vaccination she had 2 asthma attack at work. That following Friday she was not able to attend work due to shortness of breath. Saturday morning she could not inhale and couldn't stop coughing. She was then attempted to be taken to urgent care, but upon arrival she was coughing up blood and was instructed to go straight to the hospital. At the hospital upon test being done she was admitted to the covid unit and diagnosed with pneumonia due to covid 19 virus, bilateral pulmonary embolism in both lungs. She is now home in quarantine taking blood thinners for the next three months and unable to work.
COVID19 VACCINE	JANSSEN	1201418-1	40-49 years	4 days	Patient reports blood clots and longer bleeding time than usual with flossing.
COVID19 VACCINE	JANSSEN	1202290-1	18-29 years	4 days	Patient presented to hospital on 4/9/21 - 4 days post vaccination - with new onset left sided weakness. Brain CTA showed a M1 branch occlusion. Patient was given TPA and transferred to Medical Center for further management and mechanical thrombectomy. Successful thrombectomy done. Etiology of stroke cryptogenic but suspect embolic event. Questionable moyamoya disease - notes state ""if moyamoya suspect, patient will get neurosurgery service on board/appreciate neuro recommendations""
COVID19 VACCINE	JANSSEN	1205740-1	18-29 years	4 days	pulmonary embolus
COVID19 VACCINE	JANSSEN	1206311-1	65+ years	4 days	Right lower extremity DVT's and multiple bilateral pulmonary emboli involving main pulmonary arteries with right heart strain
COVID19 VACCINE	JANSSEN	1208226-1	30-39 years	4 days	DVT left leg

COVID19 VACCINE	JANSSEN	1210136-1	50-59 years	4 days	was found to have a blood clot in my left leg .
COVID19 VACCINE	JANSSEN	1214127-1	65+ years	4 days	New embolic strokes requiring hospitalization and mechanical ventilation due to mental status. New lower and upper DVT, unable to anticoagulated due to new strokes. Symptoms started acutely on day of admission, 4 days after vaccination
COVID19 VACCINE	JANSSEN	1216492-1	30-39 years	4 days	developed pain in the left popliteal fossa 4/12/2021, ED visit 4/13/2021 with doppler ultrasound positive for DVT, pt started on apixaban.
COVID19 VACCINE	JANSSEN	1222005-1	60-64 years	4 days	Pt with a pulmonary embolism 4 days post vaccine. Diagnosed in our ED.
COVID19 VACCINE	JANSSEN	1222930-1	60-64 years	4 days	Patient woke up to get ready for work and noticed blood coming out of right ear. Clots were in the blood that came out of the ear.
COVID19 VACCINE	JANSSEN	1236759-1	65+ years	4 days	Foot and ankle swelled and went to doctor - found blood clot in right leg
COVID19 VACCINE	JANSSEN	1237092-1	30-39 years	4 days	Massive pulmonary thromboemboli
COVID19 VACCINE	JANSSEN	1241572-1	40-49 years	4 days	My period was supposed to start on 04/09 the day I got the vaccine. It was delayed until 04/13 when it began to bleed BLACK clotty sticky sludge. It had the appearance and consistency of vegemite or molasses. Black sludge. At first it was extremely heavy with very large black clots. Then it became tiny little black clots suspended in a brown sludge. This continued for 6 days until 04/18. Then on 04/19 my menstruation turned bright red with no clots, but has not abated at all for another 4 days. I am currently today on Thursday 04/22 still bleeding almost 2 weeks after taking the J&J shot. I cannot believe I am still bleeding after 10 full days!!! Never in 30 years of menstruating have I had a 10 day period. I am very scared and upset.
COVID19 VACCINE	JANSSEN	1258374-1	60-64 years	4 days	4/9 thru 4/12, body aches, chills. 4/12 0400 throwing up stomach pain from dry heaving throughout the day, confusion starting at 6pm on 4/12. Seizure on 4/12 at 8 pm. 911, ambulance. to Hospital Seizure so severe caused a Fracture in the Right Scapula. MRI on 4/15 showed a venous thrombosis partial occlusion in the brain.
COVID19 VACCINE	JANSSEN	1259776-1	50-59 years	4 days	Received the vaccine on 4/4/2021. On 4/8/2021 started having pain in lower left leg. Pain off and on for two weeks. Pain intensified on 4/23/2021. I went to the emergency room where they performed on ultra sound examination of my left leg. Confirmed that I have a deep vein thrombosis (DVT) behind my left knee. Prescribed Eliquis. Saw Dr. today. He could not confirm that DVT was caused by vaccine, but I thought I should report it. I am to stay on Eliquis for six months at which time I will be evaluated for a blood clot disorder.
COVID19 VACCINE	MODERNA	0938147-1	30-39 years	4 days	I am not completely convinced that this is related to the vaccine but thought I should report it just in case. I thought I had a spider bite on my left foot, and then I thought it was shingles and then cellulitis. I was then diagnosed with a blood clot today. I have never had blood clots before.
COVID19 VACCINE	MODERNA	0952677-1	60-64 years	4 days	DVT in right leg 4 days after injection, severe pain in thigh/calf, difficulty walking Placed on Xarelto 15mg 2X daily for 21 days and then 20mg daily for 9 days. Next Doctor visit is 1/26/2021 at 9:00am Next scheduled Covid 19 vaccine is scheduled for 2/5/2021 at 7:15am
COVID19 VACCINE	MODERNA	0974068-1	65+ years	4 days	Sudden onset of severe abdominal pain with diarrhea and bloody stool/fluid on Wednesday 1/20/21. Very weak/lightheaded. To ER on evening of 1/21 - CT noted 2 Thrombi in each branch of portal vein and ischemic colitis of descending colon. No risk factors determined. Only change in life was Covid-19 Moderna vaccine. Other side effect from vaccine was only a sore are at injection site. Seen by surgery and hematology. Rapid Covid test was negative and wife's pcr Covid test was negative. As of today is feeling significantly improved but not yet taking PO and remains on heparin drip.

COVID19 VACCINE	MODERNA	0975020-1	65+ years	4 days	Had normal side effects the day after, 12/25/20 slight fever, lethargy, not even sore arm. on the 27th, felt fine. On 12/28/20, woke up not able to breath, oxygen saturation 83%, could not walk across the room without gasping for air, which lasted for about 2 days. Could not reach her PCP due to holidays, was convinced she had COVID. Went to drive-thru facility and got the COVID test on 12/28/20, negative on 12/29/20. Then made another APT, went back on 12/30/20 had negative test again. On 12/30/20 started feeling better, was not great but her O2 SAT's were about 90. Stayed that way until 1/8/21, had FU from lumpectomy with surgeon, when she got up her left ankle/foot were very swollen and red looking. Saw that Dr., and discussed the postop business and showed her the foot/leg told her to have it looked at. Her PCP was closed, she went to radiology Dept in Hospital and found DVT in her left leg. She was then told to go to the ER and ordered a CT scan, which showed pulmonary emboli in both lungs. Put on heparin IV right away, later transferred to another hospital where CV surgeon on staff. By that evening they decided that she was walking, talking and checking blood levels, kept her overnight and sent her home the next day. Needed to be on blood thinners, and saw pulmonologist. Has APT with hematologist this week. Pulm told her to call and report adverse reaction. Today, 1/26/21 her O2 SAT's are in the 99%, leg is still swollen, and is able to breath better. On Eliquis which will prevent new clots, but the others should be absorbed. Got 2nd dose on 1/21/21 and had only the classic side-effects for about 30 hours but was then fine. Had fever, chills, nausea, sore arm, cough, but then was fine. Same lot # as dose 2.
COVID19 VACCINE	MODERNA	0979630-1	40-49 years	4 days	blood clot in lungs, PE,
COVID19 VACCINE	MODERNA	0990355-1	60-64 years	4 days	DVT blood clot; A spontaneous report was received from a 60-year-old male consumer who received Moderna's COVID-19 vaccine (mRNA-1273) and developed deep vein thrombosis (DVT) blood clot. The patient's medical history, as provided by the reporter, included factor V Leiden, enlarged prostate, DVT, pulmonary embolism and hypertension. Concomitant medications reported included valsartan, alfuzosin, and acetylsalicylic acid. On 07 Jan 2021, approximately four days prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 011J20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. On 11 Jan 2021, the patient developed DVT blood clot and experienced leg pain so intense that he could not walk. A doppler exam showed the DVT was from the top of the calf to mid-thigh. Treatment for the event included a rivaroxaban starter pack with dose tapering. Action taken with mRNA-1273 in response to the event deep vein thrombosis (DVT) blood clot was not reported. The outcome of the event, DVT blood clot, was unknown.; Reporter's Comments: This case concerns a 60-year-old male patient with a relevant medical history of factor V Leiden, DVT, pulmonary embolism and hypertension who received their first of two planned doses of mRNA-1273 (Lot number: 011J20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. Patient experienced the medically significant unlisted event of Deep vein thrombosis approximately four days after administration of vaccine. Treatment for the event included rivaroxaban. Based on the temporal association between the use of the product and the event occurring after receiving the vaccine, a causal relationship cannot be excluded and the event of Deep vein thrombosis is possibly related to the product. Of note, the patient's underlying Factor V Leiden which predispose to developing abnormal blood clots, and prior medical history of DVT with pulmonary embolism are considered risk factors to the occurrence of the event.
COVID19 VACCINE	MODERNA	1042097-1	65+ years	4 days	pt did not feel ill or had mild symptoms after 2nd dose of vaccine. 4 days later patient developed fever of 101 and not controlled with acetaminophen. Temp increased to 103 and patient taken to ER and then diagnosed with pulmonary embolism. Patient still hospitalized. Not sure if related to vaccine.
COVID19 VACCINE	MODERNA	1049991-1	65+ years	4 days	4 days after receiving the vaccine in his left arm, my father developed a blood clot in his left arm that required emergency hospitalization and large doses of blood thinners.
COVID19 VACCINE	MODERNA	1085435-1	65+ years	4 days	Onset of leg pain began four days after vaccination (vaccination on 2/27 onset of leg pain 3/3). DVT behind left knee confirmed with ultrasound on 3/8 and started on apixiban 3/9. No history of clots and no activities that would contribute to an elevated risk: no family history, no recent injuries or surgeries, not sedentary, nonsmoker, and drink only in moderation.

COVID19 VACCINE	MODERNA	1092640-1	30-39 years	4 days	atrial flutter pain in right arm , pain kept going up arm but only if you touched it, got on xartorl ( blood thinner) . right forearm was really swollen , tingling and turned blue, went to hospital they did a ultrasound to check pressure in veins. if she had hand at 90 degree angel it wouldnt turn blue but if I drop it it would turn blue. next day ran more test. MRI on arm. taped vitamin c to spot where pain was in arm. developed blood clot. told her to put heat on arm and take pain meds. felt better until she stopped blood thinner feb22, 2021. two days later had more blood clots on arms, veins were showing huge in breast and foot, pants got tighter. feb 27veins in lower leg and neck started appearing more. feb28 my left hand was cold and the veins were showing more and u could see veins. right back veins started appearing , got period but after 12 hours it stopped. march 3 veins started appearing again. march 4 right arm swelled and tingling in fingers and right right arm was so painful. Nerve pain. put back on blood thinner. march 4 in evening was put on new meds. I'm still dealing with pain and different issues. march 9 had a Val moment but had tingling from butt to brain . next morning felt miserable, nauseous , throwing up and couldnt control it. 3/11 neck is swollen. referring her to university because no doctor can figure out what it is.
COVID19 VACCINE	MODERNA	1094503-1	65+ years	4 days	Four days after receiving the Moderna second dose, I had a pulmonary embolism of my right lung. It was diagnosed only on Feb. 19, as I was totally unfamiliar with the symptoms and had another indication of a problem: tachycardia, so went to the clinic. I am not sure this isn't coincidental, but I have no history of embolisms, and no family history. No one at the time of my diagnosis asked when I gotten vaccine. As I said , this may be entirely coincidental, or it may not. I am presently on eliquis blood thinners, and have had no further problems.
COVID19 VACCINE	MODERNA	1094775-1	40-49 years	4 days	Patient went to Emergency Room d/t UTI, C-diff colitis, PE/DVT admitted treated with IV heparin, Vancomycin/flagyl, antibiotics for UTI
COVID19 VACCINE	MODERNA	1099050-1	65+ years	4 days	On day 5 after injection, patient developed right inner thigh discomfort, leg swelling and accentuation of existing varicose veins.
COVID19 VACCINE	MODERNA	1105534-1	30-39 years	4 days	Tachycardia for couple of days after the vaccination. Shortness of breath since the moment of the first dose. Pain on both legs after first dose. Severe Migraines on the second dose of the vaccine that lasted for 3 weeks. Hematoma on the leg without pain, with swelling. Leg pain with warmth sensation.
COVID19 VACCINE	MODERNA	1112579-1	40-49 years	4 days	Pulmonary embolism resulting in sudden death
COVID19 VACCINE	MODERNA	1163967-1	65+ years	4 days	Felt crummy on day one and two better on day three and on day four developed four blood clots on Coumadin with an INR of 4.5 and died the next day on 3/31/2021.
COVID19 VACCINE	MODERNA	1175545-1	60-64 years	4 days	Pt devolped cough and SOB arround time of vaccine found to have PE.
COVID19 VACCINE	MODERNA	1194540-1	60-64 years	4 days	on 2/8 developed cough on 2/13 to Hospital Emergency Room, diagnosed viral pneumonia on 2/15 back to ER, admitted, diagnosed with pulmonary embolism on 2/20 to ICU, intubated and put on ventilator on 3/3 died from pneumonia due to COVID-19 per death certificate
COVID19 VACCINE	MODERNA	1204419-1	65+ years	4 days	Swelling in lower right leg, ankle, foot; Venous Doppler ordered; blood clot detected; doctor examination; Eliquis prescribed.
COVID19 VACCINE	MODERNA	1206362-1	30-39 years	4 days	05JAN21 shot #1, 08JAN21, Migraines start 08FEB21, Onset of severe abdominal pain 15FEB21, ER Visit admitted due to CT scan finding hepatic portal vein thrombosis 16-18FEB21, treated with heparin, while doing dozens of blood tests 18FEB21, discharged with Eliquis 5mg twice daily for 90 days 05MAR21, persistent migraines end Currently awaiting follow-up with heptologist and hematologist

COVID19 VACCINE	MODERNA	1207615-1	50-59 years	4 days	Presented to UCC on 3/7/2021 with complaints of left leg pain/swelling, had cervical block 03/02. when she got home she noted some groin pain, and this morning left leg was so swollen. she is also complaining of mild shortness of breath. denies chest pains, was tachy at triage. She was then transferred to Emergency Department. Per their report: The patient presents with a swollen discolored left lower leg. She does have discoloration and I am concerned for massive DVT and cerulea dolens. She does have really minimal pain to the leg except to the groin, she has intact pulses, I have low suspicion for acute ischemia/arterial clot. She does complain of some mild dyspnea with exertion above baseline so I do have concerns for possible PE. She is hemodynamically stable, appears in no distress. She is on oral contraceptives, mild obesity, no other significant VTE risk factors. I am going to empirically start her on heparin, I have also ordered a CT PE and a CT abdomen pelvis to check for proximal propagation of the DVT along with a left lower extremity duplex Doppler ultrasound. Duplex ultrasound also showed extensive left lower extremity DVT up to the common femoral, she does have bilateral PEs without evidence of significant clot burden or heart strain, she is hemodynamically stable with normal pulse oximetry. The patient also has clots proximal up to her IVC. I discussed this with Dr. of vascular surgery for possible thrombolysis therapy of the left lower extremity. She was discussed with SOUND for admission.
COVID19 VACCINE	MODERNA	1208410-1	65+ years	4 days	67-year-old male with PMH of asthma history of prostate cancer, GERD, hypertension, hyperlipidemia presents on 4/2/21 from doctor's office for evaluation of shortness of breath with exertion over the prior 3 days associated with some chest pain. He received COVID vaccine on 03/26 with Moderna vaccine (second dose) and was doing well until 3 days PTA. In the doctor's office patient had an EKG that was read as atrial flutter and doctor sent patient to the ED for rule out PE and evaluation of chest pain and shortness of breath. CTA chest showed numerous bilateral pulmonary emboli and evidence of right heart strain. Of note, his father had history of pulmonary embolism as well as rectal cancer. Patient was evaluated by pulmonologist and cardiologist and was started on full-dose anticoagulation for PE treatment. Patient did not report anything different in his life that may have contributed to development of PE (besides COVID vaccine). He denies any prior cardiac history and indicated maintaining an active lifestyle. Patient had symptomatic improvement and was discharged on full-dose rivaroxaban.
COVID19 VACCINE	MODERNA	1208618-1	40-49 years	4 days	2/5 I received the 1st does of Moderna. The next day I had a massive headache. As the days went on my neck started to hurt. The days continued and my back started to hurt. I thought my pain was just radiating down my back from my neck. ON 2/12 I have record of going to the pharmacy to get Lidocain patches. I continued on with pain from neck to middle of back. I made appointments with chiropractor and went there complaining that my back and ribs were out. This continued. On 3/5 I got the 2nd dose. I reacted as expected but this went on for 4 days. Went to a convenient care clinic where the dr ordered chest xray and D-Dimer for suspected PEs. I got a call immediately to go to ER as my D-Dimer was high at 4.3. I went back to Local ER and had a CT Scan. The CT scan showed MULTIPLE PEs with infarct. I was admitted. Since then I have been back to the ER and still struggling and have many tests coming up. My pulse is consistantly tachycardia. The ER docs do not want to entertain the thought that is was the vaccine because i was a smoker and on hormone replacement therapy. HOWEVER, I smoked for over 30 years and was on that HRT for almost 3 and never showed any signs of a clotting issue. I can pinpoint with pictures, and bank records of when the pain started and it reflects back to the 1st dose. Who knows but after the 2nd does and out of the hospital I struggled with covid symptoms including the ""foggy"" head and that continues as well as other health related PE issues. They may not want to contribute it to the vaccine but I know when this all started and it does need to be reported incase others. I have a whole story to tell that doesn't cover in writing!""

COVID19 VACCINE	MODERNA	1209054-1	50-59 years	4 days	received 2nd dose on 2/11/2021. Woke around 4AM on 2/15/2021. Noted blurry vision in left eye. By 8am had progressed to blackness starting at inner visual field and spread to total blindness by 9:30am. Went to urgent visit with optometrist. Appt was made for urgent work in with a Retinal Specialists on 4/16/2021. Diagnosed with left retinal vein thrombosis. Ordered further testing. MRI of brain and orbits, TEE, carotid ultrasound and sent to hematology/oncology for evaluation. Only finding on bloodwork was elevated homocysteine. Being treated for HTN now with Metoprolol, Amlodipine, Losarten/HCTZ, Crestor and BASA, MVI. Vision is unchanged. Blindness remains in left eye. Right eye at this point is unaffected.
COVID19 VACCINE	MODERNA	1210948-1	50-59 years	4 days	20Mar2021 - Hard bruise at injection site. (This started to disperse once on blood thinners.) 21Mar2021 - 99.3F temp 24-26Mar2021 Occasional sharp pick on interior of lower left leg. 27Mar2021 Pain and swelling on interior of lower left leg. 29Mar2021 Affected area had more than doubled in size. Called clinic and they said to go to the ER. Went to Hospital ER. Dr. diagnosed cellulitis with possible SVT. No tests done. Sent home with antibiotics. I did let the Dr. and RN know that I'd had my first vaccine. 31Mar2021 Pain in interior upper left leg. Started to notice shortness of breath. 1Apr2021 Pain in interior upper left leg. Very short of breath with activity. Had
COVID19 VACCINE	MODERNA	1214468-1	65+ years	4 days	Deep venous thrombosis. Weight loss, severe fatigue
COVID19 VACCINE	MODERNA	1269796-1	65+ years	4 days	I developed severe lower back/flank pain about 4 days after receiving my 2nd Moderna vaccination. The pain was most pronounced while lying supine and , while in that position, manifested a creeping , fluid nature, i.e. migrating from my lower back to my shoulder. I was unable to lie down comfortably. In thinking about the nature of this pain, I determined that it was possibly/probably from a PE as it seemed as if pain was migrating from my lower back to my shoulder. I'm ""not a doctor but play one on TV"" (LOL ) so surmised that it was something serious that decided that this was something needing attention. I presented to a hospital ER for care and was ultimately told I had 2 small PE blood clots - 1 in the base of each lung. My diagnosis was confirmed by a CT scan and I was subsequently admitted for observation. I was discharged the following day with blood thinners and blood pressure medication.""
COVID19 VACCINE	MODERNA	1284725-1	65+ years	4 days	Diagnosed Two Pulmonary Embolism; DVT on left leg; Coughing; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Diagnosed Two Pulmonary Embolism), DEEP VEIN THROMBOSIS (DVT on left leg) and COUGH (Coughing) in a 69-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 03-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 01-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 07-Mar-2021, the patient experienced PULMONARY EMBOLISM (Diagnosed Two Pulmonary Embolism) (seriousness criterion medically significant), DEEP VEIN THROMBOSIS (DVT on left leg) (seriousness criterion medically significant) and COUGH (Coughing) (seriousness criterion medically significant). At the time of the report, PULMONARY EMBOLISM (Diagnosed Two Pulmonary Embolism), DEEP VEIN THROMBOSIS (DVT on left leg) and COUGH (Coughing) outcome was unknown. After his 2nd dose of Moderna vaccine on 01-Apr-2021, the patient's coughing become worst again. His pulmonologist prescribed prednisone and his family physician prescribed him Azithromycin. No concomitant medications were not provided. Treatment included as Eliquis, Azithromycin, cough medicine, prednisone. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to (Patient Link).
COVID19 VACCINE	PFIZER\BIONTECH	0983350-1	50-59 years	4 days	Patient experienced a blood clot on January 11th. She is unsure if it is related to the vaccine or not.
COVID19 VACCINE	PFIZER\BIONTECH	0986749-1	65+ years	4 days	5:30 am I found husband by bed, babbling, Called 911, Had Lt Hemi Stroke. Aphasic, Rt side limp, given TPA. Sent to ICU. Recovered within 2hrs, speech, movement of extremities. It hemi dot found on ct angiogram & mri. 2nd mri found clot busted with residual. transfered to telemetry next nite. echo unconvulsive. 02 sats low, venogram done 3days later show lt dvt, lung ct wnl. Id asa & b/p meds were given. blood work to be drawn for baseline prior to anticoagulent therapy. possible d/c 9/30.
COVID19 VACCINE	PFIZER\BIONTECH	1014447-1	65+ years	4 days	Starting having Chest Pain and SOB on 2/5/21. Had oxygen saturation of 85%. Went to ICC and then ER on 2/8/21 for these symptoms.

COVID19 VACCINE	PFIZER\BIONTECH	1028827-1	18-29 years	4 days	pulmonary embolism
COVID19 VACCINE	PFIZER\BIONTECH	1033560-1	65+ years	4 days	bilateral unprovoked Pulmonary emboli
COVID19 VACCINE	PFIZER\BIONTECH	1035547-1	65+ years	4 days	left parietal CVA; left popliteal DVT; This is a spontaneous report from a contactable consumer (patient). A 71-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number= el 1284), via an unspecified route of administration on 22Jan2021 17:00 at single dose at left arm for covid-19 immunization. Medical history included cholesterol. Concomitant medications in two weeks included atorvastatin (LIPITOR), esomeprazole sodium (NEXIUM), triazolam and OTC vitamin. The patient was not diagnosed with COVID-19 prior to vaccination. On 26Jan2021 05:30 AM, the patient experienced left parietal CVA and left popliteal DVT (hospitalization, life threatening) with outcome of recovering. The patient was hospitalized for both events for 5 days. The patient underwent lab tests and procedures post vaccination which included nasal swab: unknown results. Patient received TPA (Tissue plasminogen activator), blood thinners as treatment. The adverse events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event).
COVID19 VACCINE	PFIZER\BIONTECH	1045951-1	65+ years	4 days	Stroke in third branch of middle cerebral artery and intramural clot of right carotid artery
COVID19 VACCINE	PFIZER\BIONTECH	1056640-1	65+ years	4 days	Lt parietal occlusion; DVT; Right paralysis; This is a spontaneous report from a contactable Nurse reporting for her husband. A 71-years-old male patient received the first dose of bnt162b2 (BNT162B2; Lot # EL 1284) vaccine, intramuscular in the left deltoid on 22Jan2021 17:00 at single dose for Covid-19 immunisation. The patient medical history was not reported. Concomitant medication included apixaban (APIXABAN), acetylsalicylic acid (ASPIRIN) atorvastatin (ATORVASTATIN), cyanocobalamin (CYANOCOBALAMIN), metoprolol tartrate (METOPROLOL TARTRATE), pantoprazole (PANTOPRAZOLE), sumatriptan (IMITREX [SUMATRIPTAN]), triazolam (TRIAZOLAM). The patient experienced DVT (deep vein thrombosis) on 26Jan2021 with outcome of not recovered, left parietal occlusion (ischaemic stroke) on 26Jan2021 05:30 with outcome of unknown, right paralysis on an unspecified date with outcome of unknown. The patient was hospitalized for DVT (deep vein thrombosis) and stroke from 26Jan2021 to 30Jan2021. The patient underwent lab tests and procedures including blood pressure diastolic: 84 mmhg on 30Jan2021, blood pressure systolic: 141 mmhg on 30Jan2021, body mass index: 26.4684 kg/m2 on 26Jan2021, body temperature: 98.2 °F on 30Jan2021, heart rate: 55 bpm on 30Jan2021, magnetic resonance imaging: acute left parietal lacunar infarct, Lower extremity ultrasound: left popliteal vein DVT, oxygen saturation: 95 % on 30Jan2021, respiratory rate: 18 br/min on 30Jan2021. The reporter considered the reported events to be possibly related to BNT162B2 vaccine. Follow up information has been requested.; Sender's Comments: Based on the limited information currently available, a possible contributory role of the suspect drug in the reported events cannot be completely excluded given the known suspect drug profile and/or implied temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1071744-1	30-39 years	4 days	superficial thrombophlebitis left greater saphenous vein with blood clot formation almost entire length of the vein
COVID19 VACCINE	PFIZER\BIONTECH	1075857-1	50-59 years	4 days	Blood clot on thigh
COVID19 VACCINE	PFIZER\BIONTECH	1078458-1	30-39 years	4 days	Blood clot in lung
COVID19 VACCINE	PFIZER\BIONTECH	1085323-1	65+ years	4 days	Patient started to feel right leg pain the evening of 3/2/2021, four days after receiving the COVID-19 vaccination. Patient came to the ER where a DVT was discovered in the right popliteal, peroneal, and posterior tibial veins. Patient was given apixaban 10 mg x1 and a prescription to continue apixaban outpatient. Patient was discharged from ER to home.
COVID19 VACCINE	PFIZER\BIONTECH	1086059-1	65+ years	4 days	DVT in right leg discovered after swollen foot on 2/25/2021 via ultrasound. Clot extends from mid thigh to mid calf. Placed on Xarelto 15 mg 2x/day until next imaging appointment on March 30, 2021. First incident of blood clot for mother.
COVID19 VACCINE	PFIZER\BIONTECH	1103171-1	65+ years	4 days	Pain in left leg - outside 2/7/21 went to clinic 2/8/21 Given an ultrasound Diagnosis: Blood Clot (Dvt) Given immediate shot in belly And prescription for Eliquis Followed up with Dr. (internist) 2/11/21

COVID19 VACCINE	PFIZER\BIONTECH	1103260-1	65+ years	4 days	On Sunday Feb. 21st, in the evening before bed, I noticed that my left lower leg and ankle were swollen, (as compared to my right leg.) I was also experiencing shortness of breath.
COVID19 VACCINE	PFIZER\BIONTECH	1111566-1	60-64 years	4 days	Developed extensive DVT with pulmonary emboli 4 days after receiving Covid vaccine. Clot was evacuated with thrombectomy but reaccumulated 1 day later, despite being treated with Eliquis.
COVID19 VACCINE	PFIZER\BIONTECH	1114378-1	65+ years	4 days	multiple blood clots in lungs; multiple blood clots in legs; feeling chest pain; short of breath; This is a spontaneous report from a contactable consumer (patient). A 68-year-old female patient (pregnant: No) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9269), via an unspecified route of administration in left arm on 06Feb2021 at 18:00 at single dose for covid-19 immunisation. The relevant medical history included DCIS Breast cancer from 2016, Known allergies: penicillin from an unspecified date. Concomitant medications included levothyroxine sodium (SYNTHROID). The patient previously received first dose of BNT162B2 on 16Jan2021 at the age of 68 years old (lot number: EL3249, at 06:15 PM, in Left arm) for covid-19 immunisation. The patient received 2nd Pfizer vaccine dose on Sat, 06Feb2021. On Wednesday 10Feb2021 she became short of breath. On 11Feb2021, she began feeling chest pain. On 12Feb2021, she was advised by primary care Dr to go to the emergency room. She was admitted on 12Feb2021 to ICU with multiple blood clots in her lungs and legs. She was told by the emergency Dr this was a sign of Covid, they did a Covid test, came back negative. She remained in the hospital till 18Feb2021. She was at the time of the report on Eliquis (10 mg/d). A hereditary blood clot test was done that came back negative. She had never had an issue before the vaccination with blood clots nor anyone in her family and she was in good health before the vaccination. Dr didn't think the vaccine caused the blood clots but her primary care Dr thought it did-which was why she was reporting it. The patient also stated that event multiple blood clots in her lungs and legs resulted in Emergency room/department or urgent care, Hospitalization and Life threatening illness. The patient had hospitalization for 7 days. Treatment Heparin 25,000unit in .45% NaCl Premix, Narcan received. No covid prior vaccination. The patient underwent lab test included Nasal Swab which showed negative on 12Feb2021; Hereditary blood clot test which showed negative on an unspecified date in 2021. Therapeutic measures were taken as a result of all the events. The outcome of the events was recovered with sequel.
COVID19 VACCINE	PFIZER\BIONTECH	1120515-1	65+ years	4 days	Patient had vaccine Wednesday and felt a little dizzy after the shot. Sunday morning she woke up very dizzy and ended up passing out in her kitchen while getting her morning coffee. She hit her head and was taken to the ER. Her blood pressure was found to be very high (systolic 218). CT scans revealed 2 blood clots in her lungs per pt. She was hospitalized for 2 days. She reports trouble walking now.
COVID19 VACCINE	PFIZER\BIONTECH	1122741-1	50-59 years	4 days	suspected pulmonary embolism; shock; cardiac arrest; This is a spontaneous report from a non-contactable consumer (patient's wife). A 51-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection, unknown lot number and expiration), via an unspecified route of administration on 04Mar2021 at 11:45 AM at a single dose for COVID-19 immunization. Medical history reported as none. The patient has no known allergies. The patient's concomitant medications were not reported. The patient experienced a suspected pulmonary embolism on Monday 08Mar2021 at 11:30 AM. Embolism led to shock and cardiac arrest. The patient did not have COVID prior to vaccination and was not tested for COVID post vaccination. The patient did not receive other vaccine in four weeks. The patient received unspecified treatment for the events. The patient died on 08Mar2021 at 11:30 AM. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: suspected pulmonary embolism; shock; cardiac arrest

COVID19 VACCINE	PFIZER\BIONTECH	1153524-1	50-59 years	4 days	<p>bilateral pulmonary emboli; This is a spontaneous report from a contactable Physician. A 58-year-old non-pregnant female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Lot Number: unknown, Expiration Date: unknown) via intramuscular in the left arm on 05Mar2021 10:15 AM at single dose for COVID-19 immunization. The patient's medical history included psoriatic arthritis and asthma. Patient had no known allergies. Concomitant medications were not reported. The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Lot Number: unknown, Expiration Date: unknown) on 12Feb2021 for COVID-19 immunization. On 09Mar2021 17:00 (5.00 PM), the patient experienced bilateral pulmonary emboli, which resulted in emergency room/department or urgent care, life threatening illness (immediate risk of death from the event), disability or permanent damage. The patient received blood thinners as treatment for the event. The outcome of the event was not recovered. Information on the lot/batch number has been requested. ; Sender's Comments: Based on current information available, the event bilateral pulmonary emboli mostly represented intercurrent condition in this patient with advanced age, unrelated to Bnt162b2. Relevant medical history and concurrent treatments are missing for a medically meaningful assessment.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1167965-1	65+ years	4 days	<p>Patient called PCP office 3/5 w/ c/o N/V/D, weakness and lightheaded when she stood up. Was advised to hold blood pressure medication. On 3/8, was feeling much worse and called 911. Upon arrival (8:55), patient A&amp;O x 4 with poor oxygen saturation (O2: 88%). Given nebulized albuterol/ipratropium. BG: 247mg/dl. Patient has episode of dry heaving after which she vagaled down with HR in the 40s. Recovered on her own. Once the nebulizer treatment ended, she was placed on nasal O2 at 3 liters/minutes. Given 4mg ondansetron. Lost consciousness and respirations became agonal. Pt was bagged via BVM and noted to be in PEA. CPR initiated, including intubation. Given 1mg epinephrine. NSR obtained after two rounds of CPR. Pt arrested again shortly after arrival to ED. ACLS initiated once more. Patient expired at 10:40 am.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1173932-1	65+ years	4 days	<p>Right Femoral DVT; Superficial Great Saphenous Vein Symptoms; This is a spontaneous report from a contactable physician. A 71-year-old male patient received bnt162b2 (Pfizer COVID 19 vaccine), dose 2 intramuscular on 10Mar2021 (Batch/Lot number was not reported) as single dose for COVID-19 immunisation. Medical history was not reported. The patient previously received sulfasalazine and experienced allergies. Received 1st dose of bnt162b2 (Pfizer COVID 19 vaccine) intramuscular on 12Feb2021 for COVID-19 immunisation. There were no concomitant medications. The patient experienced right femoral DVT (deep vein thrombosis) and superficial great saphenous vein symptoms on 14Mar2021, 4 days after #2 vaccination, with outcome of not recovered. Therapeutic measure taken as a result of events: Xarelto. Events resulted in doctor or other healthcare professional office/clinic visit. The patient was not diagnosed of COVID prior vaccination and has not been tested for COVID post vaccination. Information on the lot/ batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1178541-1	65+ years	4 days	<p>Started having shortness of breath on Tuesday, 9 March 2021. Continued 10 March 2021. Admitted to local hospital. Tests revealed bilateral pulmonary embolism. On Heparin drip until released 12 March 2021 on Eliquis. Difficulty breathing on Saturday, 13 March 2021. Diagnosis elevated white blood count from 9000 to 14000. Tests done. Released with antibiotics and pain meds. Nothing since then.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1190964-1	65+ years	4 days	<p>the problem was a blood clot; slight swelling of right foot; This is a spontaneous report from a contactable consumer, the patient. A 72-years-old non-pregnant female patient received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration in the left arm on 09Mar2021 13:30 (Batch/Lot number was not reported) as single dose for COVID-19 immunisation. Medical history included diabetes, high blood pressure and allergy to tape. Concomitant medications included levothyroxine; olmesartan; metformin; all were taken for an unspecified indication, start and stop date were not reported. The patient did not receive any other vaccine within four weeks prior to BNT162b2. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 13Mar2021 15:00, the patient noticed slight swelling of right foot and on 14Mar2021, the swelling increased so the patient texted the nurse who arranged appointment. The nurse said to contact the doctor and the patient spoke with registered nurse (RN) on duty who told the patient to go to the emergency room (ER) because the symptoms indicated the problem was a blood clot. The ER doctor examined and ordered an ultrasound and the results confirmed blood clot. The patient was given a prescription for blood thinner to take for 21 days (times/day, 15mg) and was told to make an appointment with the primary doctor. The patient's doctor was on spring break and she was walked in to see another doctor who said swelling looked improved and showed her where the clots were located. The patient saw her primary doctor today and she ordered a visit with a hematologist as soon as possible (ASAP) because of concerns about possible underlying issues. The outcome of events, slight swelling of right foot and the problem was a blood clot was recovering. The lot number for the vaccine, BNT162b2, was not provided and will be requested during follow up.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1192028-1	65+ years	4 days	<p>Mid Scapular Stabbing Pain; Shortness of Breath; Chest Pain; diagnosed with Bilateral PEs; Headache; Fatigue; This is a spontaneous report received from a contactable consumer (patient). A 70-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: ER8727), via an unspecified route of administration in the right arm, on 24Mar2021 (at the age of 70-years-old) as a single dose for COVID-19 immunisation. Medical history included pancreatic cancer from 2015, bilateral pulmonary embolism (PE) from 2015, and mild chronic obstructive pulmonary disease (COPD). Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient had no known allergies to medications, food, or other products. Concomitant medications, taken within 2 weeks of vaccination, included citalopram hydrochloride (CELEXA), umecidinium bromide, vilanterol trifenate (ANORO ELLIPTA), and azelastine hydrochloride (ASTEPRO). The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EN6198), in the left arm, on 03Mar2021 at 11:30 (at the age of 70-years-old) for COVID-19 immunization and experienced intense left sided neck pain and stiffness. The patient experienced headache and fatigue on 28Mar2021 and mid scapular stabbing pain, shortness of breath, chest pain, and diagnosed with bilateral PEs on 30Mar2021. The patient was hospitalized for all of the events from 30Mar2021 to 01Apr2021 for two days and the events were reported as life-threatening. It was reported that the bilateral PEs were diagnosed in the emergency department (ED). Therapeutic measures were taken as a result of all of the events, which included heparin (MANUFACTURER UNKNOWN) drip during inpatient stay and then transitioned to an unspecified treatment. The clinical outcome of headache, fatigue, mid scapular stabbing pain, shortness of breath, chest pain, and diagnosed with bilateral PEs was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1192110-1	65+ years	4 days	bilateral DVT; This is a spontaneous report from a contactable physician. An 84-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 intramuscular, administered in Arm Right on 25Mar2021 (at the age of 84-years-old) (Batch/Lot Number: EP6955) as SINGLE DOSE for covid-19 immunisation. Medical history included CKD, Allergic Rhinitis, basal cell carcinoma, vertigo, dupuytren's contracture, Gerd, hypothyroidism, hypertension, osteoarthritis, osteoporosis, prediabetic, palpitations, sleep apnea, seizures, anxiety, Allergies to medications, food, or other products: BACITRACIN, LATEX, MORPHINE, POLYSPORIN, ADHESIVE TAPE. Concomitant medication(s) included azelastine (AZELASTINE); enalapril (ENALAPRIL); famotidine (FAMOTIDINE); fluoxetine (FLUOXETINE); fluticasone (FLUTICASONE); ipratropium (IPRATROPIUM); levetiracetam; levothyroxine; zonisamide; all taken for unspecified indications, start and stop dates were not reported. The Patient was not diagnosed with Covid-19 prior to vaccination. The patient received first dose of BNT162B2 (lot number: EN6198) via intramuscular in right arm for COVID-19 immunization on 26Feb2021 at the age of 84-years-old. On 29Mar2021, the patient experienced bilateral dvt (life threatening). Therapeutic measures were taken as a result of bilateral dvt: ELIQUIS. The outcome of the event was recovering. Since the vaccination, the patient has not been tested for COVID-19. Information on Lot/Batch number is available.; Sender's Comments: There is not a reasonable possibility that event DVT is related to BNT162B2. This elderly patient had multiple underlying diseases. The event is more likely intercurrent medical condition. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1195233-1	40-49 years	4 days	Pain underneath right rib cage and difficulty breathing. It got worse over two days and then I was hospitalized. Coughed up blood. Tested with Heparin drip and now I?m on Xarelto. No previous history of blood clots. This happened three days after second vaccine
COVID19 VACCINE	PFIZER\BIONTECH	1204458-1	50-59 years	4 days	Pt received dose of vaccine on Sunday. Had business trip on Thursday. After flight became short of breath and had discomfort in the chest. Worsening on trip back
COVID19 VACCINE	PFIZER\BIONTECH	1208302-1	18-29 years	4 days	4 days after vaccination woke up with severe foot Pain. 7 days later found out this was a superficial thrombophlebitis with a gastroc DVT and 4 right subsegmental pulmonary embolisms
COVID19 VACCINE	PFIZER\BIONTECH	1208715-1	65+ years	4 days	Swollen right leg in AM four days after vaccine. Diagnosis of DVT next day, five days after vaccine. Have been on eliquis for about 4 months. Leg is still swollen. Not surprising since the covid spike protein causes blood clots.
COVID19 VACCINE	PFIZER\BIONTECH	1209216-1	50-59 years	4 days	Blood Clot-Bad swelling in right arm. Arm tingling, numbness and discolored. Arm is swollen from top of arm to fingers. Notice first sign on Monday morning (04/12/2021) when i awoke from bed around 7:00am.
COVID19 VACCINE	PFIZER\BIONTECH	1209297-1	60-64 years	4 days	2/28/21 Four days after 1st Pfizer vaccine 2/24/21 Severe cramping and swelling in my right leg and ankle. 3/9/21 Work clinic advised to seek medical attention 3/9/21 Hospital Emergency Room Diagnosis: Deep Vein Thrombosis (DVT)- Blood Clot 3/10/21 Thrombectomy Surgery & Released 3/11/21 Swelling in right leg and ankle Returned 3/12-16/21 Readmitted - Blood Clot returned Currently under several doctors care.
COVID19 VACCINE	PFIZER\BIONTECH	1212829-1	50-59 years	4 days	DVT behind the right knee that developed 3-4 days after the vaccination. I then developed a pulmonary embolism on 01/01/2021.
COVID19 VACCINE	PFIZER\BIONTECH	1218187-1	40-49 years	4 days	Six days after my second shot of Pfizer I got a DVT Clot in my left leg behind the knee. Started with Severe pain felt like a charlie horse in my left calf and foot that would not go away for more than 24 hours. My Blood pressure spiked and i got a migraine from the pain , My left leg and foot felt like stone.. The next day I called the nurse from my insurance company and she advised I go in to the hospital. Went to ER got a Ultrasound, blood tests and the ultrasound came back positive for a DVT clot. Treatment is Xarelto and follow up with my primary. Lab Results came back normal.
COVID19 VACCINE	PFIZER\BIONTECH	1219345-1	65+ years	4 days	Received second shot on April 2@ 1130am. Started with diarrhea and vomiting's on April 6 at 3:30 am. Continued to 4:30 am on April 10. Slight elevated temperature at 99.1 . On morning of April 11 couldn't put pressure on right side, leg and arm, facial numbness. Went to er and they said I was having a stoke, transferred to hospital. MRI done verified Stroke with blood clot to Left thalamus Sent home and will be receiving PT and OT.

COVID19 VACCINE	PFIZER\BIONTECH	1227967-1	18-29 years	4 days	<p>This is a spontaneous report from a contactable consumer (patient). An 19-year-old female patient (not pregnant at event onset and time of vaccination) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number and expiration date unknown) via an unspecified route of administration at left arm on 11Feb2021 at 00:00 (19-year-old at time of vaccination), at single dose, for COVID-19 immunization. The patient's medical history included Ewing Sarcoma which was not ongoing (Diagnosed at 5 years old, treated with chemotherapy for 1 year, cancer free for 13 years). There were no known allergies. Concomitant medications included low dose ethinylestradiol, norgestimate (TRI-SPRINTEC) and montelukast sodium (SINGULAIR). No other vaccine in four weeks. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number and expiration date unknown) via an unspecified route of administration at left arm on 20Jan2021 at 00:00 (19-year-old at time of vaccination), at single dose, for COVID-19 immunization. Starting 15Feb2021 at 12:00, the patient began to have shortness of breath that got progressively worse throughout the week. On 22Feb2021, she woke up with severe shortness of breath and her O2 saturation was 82%. She went to the hospital emergency department and was given a chest CT, and diagnosed with large bilateral pulmonary embolisms. She also had severe right ventricular strain due to the PEs. She was rushed into an EKOS procedure and a IVC filter was also put in. Adverse events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization (4 days), and Life threatening illness (immediate risk of death from the event). COVID test (test type: Nasal Swab, test name: Novel Coronavirus PCR) post vaccination was Negative on 22Feb2021, and Negative on 29Mar2021. Therapeutic measures were taken as a result of the events and included Heparin drip, EKOS and IVC filter procedure. The outcome of the events was recovering. Information on the lot/batch number has been requested.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1235823-1	65+ years	4 days	<p>DVT in right leg from calf to thigh; small blood clots; swollen right leg; This is a spontaneous report from a contactable consumer (patient). A 69-year-old male patient received bnt162b2 (BNT162B2; lot unknown: Not available/provided to reporter at the time of report completion), dose 1 via an unspecified route of administration, administered in Arm Left on 20Jan2021 14:00 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunization, at the age at vaccination of 68 years old. Medical history included high blood pressure from an unknown date and unknown if ongoing. No other vaccine in four weeks. Patient had no known allergies. Concomitant medications included losartan taken for an unspecified indication, start and stop date were not reported. The patient experienced dvt in right leg from calf to thigh on 25Jan2021 with outcome of not recovered, small blood clots on 25Jan2021 with outcome of not recovered, swollen right leg on 24Jan2021 10:00 AM with outcome of not recovered. Reported four days after the first vaccine, swollen right leg. Five days after the first vaccine, diagnosed with DVT in right leg from calf to thigh. Small blood clots. Events resulted in: Doctor or other healthcare professional office/clinic visit, Life threatening illness (immediate risk of death from the event). No Covid prior vaccination. No Covid tested post vaccination. Therapeutic measures were taken as a result of events included: Eliquis. Information on the lot/batch number has been requested.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1265987-1	30-39 years	4 days	<p>4 days later minor blood clot in my finger (not sure it is drug related); Bruise at site of injection; This is a spontaneous report from a non-contactable consumer (patient). A 35-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 09Apr2021 (Batch/Lot number was not reported) as SINGLE DOSE for COVID-19 immunization. Medical history and concomitant medications were not reported. On 13Apr2021, the patient had bruise at site of injection and 4 days later (17Apr2021) minor blood clot in her finger was noted (not sure it was drug related). The patient had no COVID-19 prior vaccination and not tested post vaccination. The patient requires doctor or other healthcare professional office/clinic visit for the events and unknown if treatment was received. The patient had not yet recovered from the events. No follow up attempts are possible. information about lot/batch number cannot be obtained</p>

COVID19 VACCINE	PFIZER\BIONTECH	1266075-1	40-49 years	4 days	Multiple blood clots in the left leg had to be submitted to the Emergency Room at the hospital for immediate treatment; This is a spontaneous report from a non-contactable consumer. A 40-years-old male patient received 1 dose of bnt162b2 ((PFIZER-BIONTECH COVID-19 VACCINE) lot number: ER2613 via an unspecified route of administration, in arm left on 12Apr2021 at the age of 40 years as SINGLE DOSE for covid-19 immunization. The patient medical history was not reported. There were no concomitant medications. The patient experienced multiple blood clots in the left leg and he had to be submitted to the emergency room at the hospital for immediate treatment on 16Apr2021 12:00 with outcome of recovering. The patient was hospitalized for 2 days and was treated with unspecified treatment. Covid test post vaccination: Nasal Swab on 20Apr2021 result Negative No follow-up attempts are possible. No further information is expected.
COVID19 VACCINE	PFIZER\BIONTECH	1269546-1	40-49 years	4 days	Portal Vein Thrombosis; abdominal pain; This is a spontaneous report from a contactable consumer (patient). A 49-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EN6206 and expiration date not provided), via an unspecified route of administration, administered in Arm Left first dose on 18Mar2021 17:00 at single dose for covid-19 immunisation. The patient's medical history included obesity. There were no concomitant medications. About four days after vaccine on 22Mar2021, the patient started having abdominal pain. On 31Mar2021, the pain caused the patient to go to the ER and physician office visit, where the patient was diagnosed with a portal vein thrombosis. The patient was then hospitalized for 2 days. The patient was treated with Eliquis. The outcome of the events was recovering.
COVID19 VACCINE	PFIZER\BIONTECH	1284761-1	50-59 years	4 days	blood clot at upper right chest underneath collar bone; Swollen right arm and fingers; tingling and numbness in arm; numbness in arm; headaches; This is a spontaneous report from a contactable consumer (patient). A 56-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) dose 1 via an unspecified route of administration, administered in Arm Left on 08Apr2021 04:00 (Lot Number: EWO153) as SINGLE DOSE for covid-19 immunisation. Medical history included Implantable cardioverter defibrillator insertion from 2005. Concomitant medication in two weeks included verapamil 120 mg. No other vaccine in four weeks. No Covid prior vaccination. No Covid tested post vaccination. No Known allergies. On 12Apr2021, the patient experienced blood clot at upper right chest underneath collar bone. Swollen right arm and fingers with tingling and numbness in arm. Also, suffering from occasionally headaches. The patient was relatively healthy with no know blood clot issues. Events resulted in Doctor or other healthcare professional office or clinic visit. Unknown if treatment was received for events. The outcome of events was not recovered.

COVID19 VACCINE	PFIZER\BIONTECH	1291268-1	50-59 years	4 days	This is a spontaneous report from a contactable consumer (patient). A 59-year-old male patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER8732) at the age of 59-years-old, via an unspecified route of administration in left arm on 22Mar2021 at 15:00 at single dose for COVID-19 immunisation. The patient's medical history was reported as none. He has no known allergies and has COVID prior to vaccination. Concomitant medications included metoprolol, rosuvastatin, oxybutynin, and tamsulosin. There were no other vaccines in four weeks and no additional vaccines administered on the same date of the COVID-19 vaccine. The patient reported that he was having some wild effects from the vaccine and did not know what to do. On 26Mar2021 at 15:00, he was having neuropathy like effects. His hands, arms, legs, and feet were experiencing pain and burning sensations, they were burning like nerve damage; he also has a little burning sensation in his nose and cheeks. He has never had this before. The events resulted in doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. He was also having some weird sensations in his calf muscles, these sensations started within the past week and a half (Apr2021) which prompted physician office visit. The physician placed him on gabapentin 100 mg to start from 12Apr2021, but it was not enough, it was titrated up to 300 mg, three times a day and he is scheduled to see specialist soon. The patient mentioned that this vaccine has ruined his health. He also went to an urgent care center because his leg was bothering him, it was swelling on an unspecified date in 2021; he thought he had a blood clot; they did some kind of test where they looked at the leg and did not find anything. He didn't have a particular question. He would just like to talk to someone to see if this was going on with anyone else, if it will go away, or if this was permanent problem he will have. The patient was not tested for COVID post vaccination. He received his second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EW0161), via an unspecified route of administration in left arm on 13Apr2021 at 15:00 at single dose for COVID-19 immunisation. The outcome of the events was not recovered.
COVID19 VACCINE	JANSEN	1177000-1	40-49 years	5 days	Doctor determined superficial thrombophlebitis on left hand where IV 4 weeks before was taken out while at ER for kidney stone 2/18/2021. Hand was somewhat sore for weeks before vaccine. J & J vaccine on 3/12/2021. 5 days later 5/17/2021 left hand very painful and huge blood clot. Went to doctor and diagnosed blood clot and prescribed clindamycin 300 mg 3X a day for 7 days. It wasn't until the 7th day the pain was gone and swelling of the vein back to normal.
COVID19 VACCINE	JANSEN	1202184-1	60-64 years	5 days	Blood clots in both lungs. Admitted to the hospital with severe pain in chest, trouble breathing, within 5 days of vaccination. Put on blood thinners to help get rid of the clots. Extreme fatigue before admittance to the hospital as well as ongoing extreme fatigue.
COVID19 VACCINE	JANSEN	1203460-1	40-49 years	5 days	Pt had Covid in November 2020. He was in the hospital and had blood clots in the left leg.
COVID19 VACCINE	JANSEN	1204650-1	65+ years	5 days	On Tuesday March 16 started having difficulty breathing went to ER. Blood Clots in both lungs. Was admitted and was treated in hospital until Friday March 19.
COVID19 VACCINE	JANSEN	1205086-1	60-64 years	5 days	Patient's husband called to report that his wife was in the hospital due to a blood clot that formed in her leg. He stated that she was having organ failure. Patient is currently being treated at a local hospital for blood clots that were moving and affecting her organs.
COVID19 VACCINE	JANSEN	1207793-1	40-49 years	5 days	About a month after the shot, I developed a blood clot in my lung. The clot was found by a CT scan. I am currently taking Eloquis to hopefully dissolve the clot. I have been overly tired with little energy and some muscle/body aches.
COVID19 VACCINE	JANSEN	1207990-1	30-39 years	5 days	Patient developed left leg pain 5 days after the vaccine, with tightness behind the knee, and then soon developed swelling. As pain improved he did not seek attention until today, 4/14/2021 and was found to have a severe large fully extensive and occlusive femoral DVT L leg.
COVID19 VACCINE	JANSEN	1208800-1	50-59 years	5 days	Became short of breath a few days later, diagnosed with bilateral pulmonary embolism on 3/10/21 at Medical Center
COVID19 VACCINE	JANSEN	1210244-1	65+ years	5 days	Left Popliteal DVT Edema, pain, increased warmth Starting Eliquis 10mg po bid x 7 days f/b 5mg bid x 6 months
COVID19 VACCINE	JANSEN	1211831-1	50-59 years	5 days	Have blood clot in right leg now on blood thinners
COVID19 VACCINE	JANSEN	1212147-1	40-49 years	5 days	Patient presented with leg pain and shortness of breath to the emergency department. Was subsequently found to have a DVT

COVID19 VACCINE	JANSEN	1220134-1	50-59 years	5 days	Bilateral Pulmonary Embolism: Symptoms began acutely at 8pm on 4/12/2021. She developed chest pain, shortness of breath and nausea. Sharp pain. She was seen in the emergency department and at that time D-dimer was elevated to 1338. She had a subsequent CT scan that showed Subsegmental pulmonary emboli in posterior basal segments of lower lobe bilaterally
COVID19 VACCINE	JANSEN	1220793-1	65+ years	5 days	04/0821 resident receive J&J Covid vaccine at the facility in the left deltoid and on 4/13/21 swelling was noted to her left upper and lower extremities. Physician was notified and orders were obtained to perform a Doppler of the affected extremities and to commence Eliquis 5mg po bid . 1st dose of Eliquis was administered on 4/13/2021 @ 1900-2300.
COVID19 VACCINE	JANSEN	1221257-1	40-49 years	5 days	On April 7th in the morning, I woke with sharp pain in right calf. It was not swollen, discolored, or hot. I had not participated in any activity recently that I felt caused an injury. I took Advil and Tylenol and rested for a few days, but the pain got worse. On April 14th, after reading reports on some adverse affects from the J&J vaccine, I made an appointment to see my primary physician. After blood work and an ultrasound, I was diagnosed with a DVT in my right calf. I have a started a 90-day cycle of Xarelto to treatment the DVT.
COVID19 VACCINE	JANSEN	1223111-1	60-64 years	5 days	Patient had severe pain in one leg since 03/14/2021 Went to the emergency room on 03/21/2021 where he was notified that he had a clot in his lung. It caused a bilateral pulmonary embolism.
COVID19 VACCINE	JANSEN	1223432-1	40-49 years	5 days	CVA and cerebral venous sinus thrombosis
COVID19 VACCINE	JANSEN	1223575-1	50-59 years	5 days	Left popliteal DVT
COVID19 VACCINE	JANSEN	1229090-1	65+ years	5 days	Pt noticed his calf was swollen and had some pain/tenderness on Wednesday. He then went back to the clinic on Friday where they instructed him to report to the ER. At the ER he was diagnosed with a DVT and told to begin Eliquis that night.
COVID19 VACCINE	JANSEN	1229939-1	40-49 years	5 days	DVT diagnosed 7 days after vaccine. Pt does have hx of DVT in past and was dx'd with COVID by NAAT at same time. Otherwise no risk factors.
COVID19 VACCINE	JANSEN	1230912-1	40-49 years	5 days	Cavernous Sinus Thrombosis, Right Jugular Thrombosis, Pulmonary Embolism, thrombocytopenia (20K)
COVID19 VACCINE	JANSEN	1232763-1	50-59 years	5 days	On 3/17/21 patient returned to clinic complaining of sudden onset of dizziness, weakness, shaking, some SOB and anxiety. Patient reports this started suddenly at noon. She reports associated lightheadedness and difficulty with focusing her vision. She reports ""feeling like I am going to pass out and not wake up"". Denies nausea, vomiting, head injury, fall, slurred speech, confusion, or chest pain. Last meal was previous night, has not eaten that day. She denies recent alcohol use, did admit to smoking marijuana prior to episode starting. She did have the Johnson&Johnson Covid vaccine on 3/12/21, only has had a sore left arm, denies other side effects. Patient was sent to the emergency department via ambulance for further evaluation. Work up at the emergency department showed bilateral pulmonary embolisms.""
COVID19 VACCINE	JANSEN	1234252-1	30-39 years	5 days	Lower extremity DVT
COVID19 VACCINE	JANSEN	1236681-1	60-64 years	5 days	RLE DVT-Acute, occlusive deep vein thrombosis in the right gastrocnemius vein-started on anticoagulant-apixaban
COVID19 VACCINE	JANSEN	1237936-1	40-49 years	5 days	Blood clot in right arm , SOB, CHEST PAIN, arm pain,
COVID19 VACCINE	JANSEN	1241772-1	60-64 years	5 days	I have severe swelling in both legs from knee to my feet, severe itching and hives, legs have blistered and burst open. I also have a Blood clot in my lower left leg. Have tried 2 kinds of antibiotics, I am on Xarelto 10 mg tab for the blood clot
COVID19 VACCINE	JANSEN	1242755-1	50-59 years	5 days	Developed transient SOB on 4/16 that resolved on 4/18. Developed left leg pain and swelling on 4/19. LE ultrasound revealed extensive DVT. Does report a 4 hour plane ride 4 weeks ago.

COVID19 VACCINE	JANSEN	1260946-1	50-59 years	5 days	Patient had a syncopal episode while on the toilet and moving her bowels on night of 4/15. She struck head and sustained left peri-orbital laceration. Was seen at ER on 4/16. Had CT of head showing cutaneous injury only. Was discharged home. On 4/20 she first noted swelling in right calf. This worsened and was seen in Care Center on 4/23. Had high D-dimer and had ultrasound of leg at ER. This showed right leg DVT extending from the distal femoral vein through the popliteal and posterior tibial veins. She had a long wait and left. She called PCP's on 4/24 on was prescribed Eliquis. She had trouble getting prescription filled due to cost and need for insurance pre-approval. Finally picked up and started Eliquis on the morning of 4/25. She contacted PCP's office on morning of 4/26 with new complaint of ""terrible shortness of breath and lightheadedness"". Patient was seen. CTA of chest done at hospital. showed ""a large bilateral acute bilateral pulmonary embolism with saddle embolus, involving the right and left main pulmonary arteries, as well as the lateral lower lobe, upper lobe, right middle lobe, and lingular segmental and subsegmental branches. There is slight bowing of the interatrial ventricular septum to the left consistent with right heart strain."" Patient to be admitted for thrombectomy""
COVID19 VACCINE	JANSEN	1261010-1	65+ years	5 days	Deep Vein Thrombosis right leg. Five days after being vaccinated I began to notice swelling in my right leg from my knee through my ankle-foot area. There was an associated increase in pain in the knee. I tried to shake it off hoping that the swelling and pain would go away, but I finally relented to the concerns of my family and sought care on the 6th of April at the emergency room because my doctor refused an in-person appointment. The emergency room physician prescribed Eliquis which I have been taking. The swelling seems to have leveled off, but my right leg still appears to be twice the size of my left leg
COVID19 VACCINE	JANSEN	1263180-1	60-64 years	5 days	Increase short of breadth, chest pain, & blood clog
COVID19 VACCINE	JANSEN	1266799-1	30-39 years	5 days	Venous thrombosis of proximal greater saphenous vein
COVID19 VACCINE	JANSEN	1271106-1	50-59 years	5 days	Pain in both pelvic limbs, left predominance, admitted to hospital for observation, admission April 23, discharged April 25, next appointment to angiologist May 3
COVID19 VACCINE	JANSEN	1271703-1	50-59 years	5 days	Blood clot in right wrist area: On the evening of 3/17/21, I felt sudden pain in the palm of my right hand, just above the wrist. Then the vein just below my wrist swelled up and turned blue. The next morning when I woke, the vein was no longer swollen, but the area below my wrist had a large bruise, which lasted several days. I contacted my physician that day (3/18) who said just to monitor/observe and come in if continuing issues (which there were not).
COVID19 VACCINE	JANSEN	1280011-1	65+ years	5 days	Blood clot in the brain resulting in inter-cranial bleeding... affected speech, processing , vision
COVID19 VACCINE	JANSEN	1286066-1	50-59 years	5 days	Cough, fatigue and dyspnea on 3/22/21 ER visit on 4/1/21 diagnosed with COVID pneumonia Pain and swelling in right leg Positive for DVT in lower extremity Hospitalized and diagnosed with PE
COVID19 VACCINE	JANSEN	1289024-1	50-59 years	5 days	5 days after shot, vision in left eye became blurry- went to primary eye doctors- sent to Surgeons- determined a blood clot in the back of the eye
COVID19 VACCINE	JANSEN	1289051-1	50-59 years	5 days	As pt's PCP office, we became aware that pt was admitted to hospital on 5/3/21 with dx of pulmonary embolism. Per admission note, pt reporting increased shortness of breath x 4 days prior to his admission date. Also noted to have received J&J vaccine on 4/29/21. Pt still currently admitted to the hospital and undergoing treatment for PE.
COVID19 VACCINE	MODERNA	0925358-1	50-59 years	5 days	Developed left lower leg discomfort on day 5 post-vaccination with dose 1 of Moderna COVID-19 vaccine. Developed worsening pain, swelling and mild erythema of the left lower leg distal to the knee over the next 48 hours. Seen on 1/05/2021, and STAT venous duplex ultrasound ordered, which revealed a prominent deep vein thrombosis partially occlusive, partially nonocclusive extending from the left femoral vein distally. Started on anticoagulation with apixiban. No signs/symptoms of pulmonary embolus. No precipitating event that would raise risk of acute DVT (He does not have any open areas of his skin concerning for infection in the leg. No recent injury to the leg. No recent surgeries or period of immobility. No prior personal history of DVT, provoked or unprovoked. He does not smoke. He does drink alcohol in small amounts, to moderate amounts on occasion. No history of alcohol misuse or abuse.). He has chronic HIV infection, well controlled. He does have a family history of DVT (his mother had 1 provoked and 1 non-provoked DVT).
COVID19 VACCINE	MODERNA	0941080-1	65+ years	5 days	5 days after Moderna vaccine, developed severe abd pain, mid epigastrium. No Nausea or vomiting. No fever. Mild diarrhea. after 48 hrs with no improvement went to ED

COVID19 VACCINE	MODERNA	0946978-1	40-49 years	5 days	Onset of shortness of breath and cough on 1/3 that progressively got worse. Clinical diagnosis of pneumonia without fever was made, patient started azithromycin on 1/5 and albuterol treatments every 4-6 hrs. Initially he improved, but then worsened. chest xray on 1/6 was negative for pneumonia, PCR covid test was negative, albuterol treatment did not bring much relief. He started respiratory distress on 1/10 and was taken by car to the local ER where another covid test was negative and chest CT revealed multiple bilateral pulmonary emboli. The leg US revealed blood clots in both of his legs. He had an emergency catheter-delivered thrombolysis and was discharged home from the ICU on 1/12 on oral anticoagulants. He is gradually improving, but very weak. He tires easily and gets a drop in oxygen to 90- 93%, as well as an increase in the heart rate to 120 when walking less than half a mile. He runs out of breath with exertion.
COVID19 VACCINE	MODERNA	0953594-1	40-49 years	5 days	Vaccinated 1/6/2021. No issues reported per client until day 5, 1/11/2021. Reports lymphadenopathy, axillary area, left side, left breast area and chest. Reports some swelling noted lymph nodes right axillary and sore to touch. Report fever onset 1/11, 1/12, 1/13. Then Thursday 1/14/2021 contacted PCP and was told on 1/15/2021 to see medical evaluation. Reports on 1/15/2021 went to ER and was evaluated. Reports lymphadenopathy and ""small P.E."" found. Unsure if incidental as history of P.E. 4 years ago. Also reports over 25 years ago had lymphadenopathy from Flu Vaccine and has not had any vaccines prior to this COVID-19 vaccine. Reports discharged same day to home with Topical Benadryl Cream for redness and itching at site of injection which per client also did not start until day #5 after vaccination. Reports no issues prior to day #5 post vaccination. Home and doing better but with continued lymphadenopathy left side axillary, breast and chest area. Denies any follow-up appointments other than a request to talk w/LHD Doctor to see if she should get vaccine #2. This RN will relay to MD for advisement/consult.""
COVID19 VACCINE	MODERNA	0974032-1	50-59 years	5 days	Left calf pain and swelling, +DVT
COVID19 VACCINE	MODERNA	1002441-1	65+ years	5 days	On morning of 1/30/21 patient presented with confusion, unilateral weakness - diagnosed and admitted with CVA - embolism of R middle cerebral artery per CT scan. Noted to be in atrial fibrillation during admission. Discharged to rehab center on 2/3/21.
COVID19 VACCINE	MODERNA	1011384-1	30-39 years	5 days	Pulmonary Embolism, hospitalized from 2/2/2021-2/3/2021. Received anti-coagulants and will remain on anti-coagulants for at least 3 months.
COVID19 VACCINE	MODERNA	1036912-1	50-59 years	5 days	Initial injection site pain for two days. Around day five, both armpits were discolored significantly. On day nine I was in the ER with left side abdominal cramps that was diagnosed after a CT Scan as a splenic infarction caused by a blot clot. I have not had a blot clot previously and have always been healthy with no surgeries or prescription medications except propranolol for anxiety (since the pandemic started).
COVID19 VACCINE	MODERNA	1053378-1	50-59 years	5 days	Patient presented on 2/24/21 with B pulmonary emboli, with symptoms of dyspnea started around 2/22/2021, she was have headache, dizziness and abdominal bloating on presentation.
COVID19 VACCINE	MODERNA	1060219-1	65+ years	5 days	Trouble breathing, severe fatigue, blood clots in lung and leg.
COVID19 VACCINE	MODERNA	1093487-1	50-59 years	5 days	Thrombosis of the vein branch of the left eye.
COVID19 VACCINE	MODERNA	1095766-1	65+ years	5 days	My mother felt pain increasing in her back. On Saturday the 6th she went to her clinic Dr. He gave her a x-ray. He saw a mass and told her to go to the hospital for more test. She went to hospital where they per f order a CT scan and many other test and found a blood clot on her lungs. She was advised to be admitted immediately. She was there getting many test taking blood thinners to shrink the clot. Monday after all her test came back the doctors could not find a source of the clot. She was sent home with blood thinner prescriptions and follow up appointments.
COVID19 VACCINE	MODERNA	1112041-1	65+ years	5 days	Patient was awakened at 0400 on 3/18/2021, with shortness of breath and her entire right side hurting. Pain was in the lower right chest, right upper abdominal quadrant and right flank pain. Presented to the ED. CT of chest /abdomen showed pulmonary embolus in the right lower lung. Patient is being treated with Eliquis and was sent home from the ED on 3/18.
COVID19 VACCINE	MODERNA	1115412-1	65+ years	5 days	Pulmonary embolism starting March 1
COVID19 VACCINE	MODERNA	1124370-1	50-59 years	5 days	nonocclusive left sigmoid venous sinus thrombosis without ischemic stroke

COVID19 VACCINE	MODERNA	1131203-1	Unknown	5 days	blood clots that had apparently broken up and gotten stuck in my lungs; A spontaneous report was received from a consumer who is a male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced blood clots that had apparently broken up and gotten stuck in lungs/thrombosis/pulmonary embolism. The patient's medical history was not provided. No relevant concomitant medications were reported. On 04 Mar 2021, prior to the onset of the events, the patient received the first of two planned doses of mRNA-1273 (Lot number: not provided) intramuscularly for prophylaxis of COVID-19 infection. On 09 Mar 2021, five days post-vaccination, the patient reported he had a significant event in which his wife had to call an ambulance and rush him to the hospital. It was discovered that he had blood clots that had broken up and got stuck in his lungs. The patient reported he was put on heparin and apixaban blood thinners. The patient stated he is scheduled for further testing. Treatment included, heparin and apixaban. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, blood clots that had apparently broken up and gotten stuck in my lungs/thrombosis/pulmonary embolism, were considered unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1143895-1	50-59 years	5 days	13th of January received first Moderna shot. 18-19th began to have headaches 22nd headaches worsened 25th at the doctor's (tested negative nose swab) home till 28th (28th tested positive for corona after having her first shot at Advent) stroke symptoms at school 28th Advent did CT scan MRI venous thrombosis diagnosis, from front to back, hemorrhage in the northern hemisphere 29th blood thinner administered to attempt to drain clot, seizures 31st passed away
COVID19 VACCINE	MODERNA	1152775-1	60-64 years	5 days	presented 5 days after Covid vaccine with massive pulmonary emboli
COVID19 VACCINE	MODERNA	1153985-1	65+ years	5 days	Blood clot in the lung; A spontaneous report was received from a consumer concerning a 70-years-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced blood clot in the lung/ Pulmonary thrombosis. The patient's medical history included hyperthyroidism. Products known to have been used by the patient, within two weeks prior to the event, included levothyroxine for hyperthyroidism. On 10 Mar 2021, approximately five days prior to the onset of the events, the patient received the first of two planned doses of mRNA-1273 (Batch number not provided) via unknown route for prophylaxis of COVID-19 infection. On 15 Mar 2021, the patient developed a medically significant event of blood clot in her lung and was hospitalized for 2 days followed by short of breath and cannot walk very far. Treatment for the event included blood thinner. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the event, blood clot in the lung/t Pulmonary thrombosis was not provided.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1156535-1	50-59 years	5 days	Experienced a heart attack on the evening of March 23, 2021 quickly followed by cardiac arrest. Was resuscitated during transport to the hospital. The hospital discovered a coronary artery embolism with myocardial infarction. I was taking a blood thinner at the time so the blood clot should not have formed to begin with. No heart disease was found and once clot was removed by heart function returned. I had had my first COVID-19 shot the Thursday before the event so I thought I should report the event in case there's a connection.
COVID19 VACCINE	MODERNA	1160923-1	65+ years	5 days	5 days after second Moderna Covid vaccination, patient had sudden onset severe right leg swelling and pain, found to have extensive right lower extremity DVT and bilateral pulmonary embolism
COVID19 VACCINE	MODERNA	1181643-1	40-49 years	5 days	Patient experienced a non-itching, non-blanching petechial rash across bilateral arms, trunk, and back beginning 5 days after vaccination. Biopsy revealed underlying vasculitis with eosinophils. The rash clears up with use of oral prednisone. Patient has also experienced edema and ulcers of the lower extremities believed to be caused by microbeoli associated with vasculitis.

COVID19 VACCINE	MODERNA	1194136-1	Unknown	5 days	was hospitalized with multiple blood clots; This spontaneous case was reported by a physician and describes the occurrence of THROMBOSIS (was hospitalized with multiple blood clots) in a 61-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 017B21A) for COVID-19 vaccination. The patient's past medical history included Surgery (on his shoulder.) on 12-Mar-2021. On 26-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 31-Mar-2021, the patient experienced THROMBOSIS (was hospitalized with multiple blood clots) (seriousness criterion hospitalization). At the time of the report, THROMBOSIS (was hospitalized with multiple blood clots) had not resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant drugs were not reported. Treatment information was not provided.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the reported event of thrombosis, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1194290-1	65+ years	5 days	my mother collapsed in the kitchen she was rushed to hospital via ambulance she passed away, doctor said her heart was having a hard time he said there was a blood cot by lung
COVID19 VACCINE	MODERNA	1203769-1	65+ years	5 days	On 3/11, patient complained of shortness of breath with ambulation. She was sent to the ED and diagnosed with pulmonary embolism. Negative for DVT.
COVID19 VACCINE	MODERNA	1203783-1	60-64 years	5 days	Pulmonary embolism resulting in atrial fibrillation with rapid ventricular response. Hospital treatment included IV anticoagulation, IV anti arrhythmic medications, and subsequent cardioversion.
COVID19 VACCINE	MODERNA	1206937-1	65+ years	5 days	Pt received her 1st Moderna covid 19 vaccination on 3/12/21. She developed sudden Left lower extremity swelling on 3/17 which progressed to her hospitalization for a left lower extremity DVT on 4/6/21. she was placed on eliquiss and eventually discharged home.
COVID19 VACCINE	MODERNA	1208349-1	65+ years	5 days	pulmonary embolism. three subsegmental emboli, right lung
COVID19 VACCINE	MODERNA	1220870-1	65+ years	5 days	Cardiac arrest; pulmonary embolism; This spontaneous case was reported by a consumer and describes the occurrence of CARDIAC ARREST (Cardiac arrest) and PULMONARY EMBOLISM (pulmonary embolism) in a 72-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Resuscitation. On 04-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Mar-2021, the patient experienced CARDIAC ARREST (Cardiac arrest) (seriousness criteria hospitalization, medically significant and life threatening) and PULMONARY EMBOLISM (pulmonary embolism) (seriousness criteria hospitalization and life threatening). At the time of the report, CARDIAC ARREST (Cardiac arrest) and PULMONARY EMBOLISM (pulmonary embolism) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

COVID19 VACCINE	MODERNA	1249666-1	40-49 years	5 days	This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of CEREBRAL VENOUS SINUS THROMBOSIS (Cerebral Venous Sinus Thrombosis) and HEADACHE (headache) in a 42-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 016B21A) for COVID-19 vaccination. Concomitant products included ETHINYLESTRADIOL, NORGESTREL (CONTRACEPTIVE HD) for Birth control. On 25-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 30-Mar-2021, the patient experienced HEADACHE (headache) (seriousness criterion hospitalization prolonged). On 02-Apr-2021, the patient experienced CEREBRAL VENOUS SINUS THROMBOSIS (Cerebral Venous Sinus Thrombosis) (seriousness criterion hospitalization prolonged). The patient was hospitalized from 02-Apr-2021 to 06-Apr-2021 due to CEREBRAL VENOUS SINUS THROMBOSIS and HEADACHE. At the time of the report, CEREBRAL VENOUS SINUS THROMBOSIS (Cerebral Venous Sinus Thrombosis) had not resolved, and HEADACHE (headache) outcome was unknown. Not Provided, DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Apr-2021, Computerized tomogram: abnormal (abnormal) Cerebral Venous Thrombosis in the brain. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment of the events included Pradaxa. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, the patient's recent history of starting back on oral contraceptives may remain a risk factor for this event.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, the patient's recent history of starting back on oral contraceptives may remain a risk factor for this event.
COVID19 VACCINE	MODERNA	1284727-1	65+ years	5 days	heart attack; Bood clot; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of MYOCARDIAL INFARCTION (heart attack) and THROMBOSIS (Bood clot) in a 67-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 18-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Mar-2021, the patient experienced MYOCARDIAL INFARCTION (heart attack) (seriousness criteria death and medically significant) and THROMBOSIS (Bood clot) (seriousness criterion death). The patient died on 23-Mar-2021. The reported cause of death was Heart attack and Clot blood. It is unknown if an autopsy was performed. Not Provided No concomitant medication were reported. No treatment information was provided.; Reported Cause(s) of Death: Heart attack; Clot blood
COVID19 VACCINE	MODERNA	1294073-1	Unknown	5 days	Blood clots in both lungs; Swelling in left breast; The arm showed Small spots; This spontaneous case was reported by a consumer and describes the occurrence of DEEP VEIN THROMBOSIS (Blood clots in both lungs) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 15-Feb-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced DEEP VEIN THROMBOSIS (Blood clots in both lungs) (seriousness criterion medically significant). At the time of the report, DEEP VEIN THROMBOSIS (Blood clots in both lungs) outcome was unknown. No concomitant medications were reported. Treatment of the events were not reported. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 28-Apr-2021: Follow up received on 28APR2021 included a new event of ""blood clots in both legs"" - making this case serious.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.""
COVID19 VACCINE	PFIZER\BIONTECH	0956642-1	40-49 years	5 days	Visited Provider appx 500 pm 1.14.2021 DVT - left calf - 2 clots via ultrasound on Eliquis now
COVID19 VACCINE	PFIZER\BIONTECH	0975052-1	30-39 years	5 days	Blood clot, DVT of a ill art vein acute left

COVID19 VACCINE	PFIZER\BIONTECH	1015672-1	65+ years	5 days	my body collapsed and I had a Pulmonary embolism/I have clot in my lung; I have behind my knee like a deep wide black spot and it is hard; This is a spontaneous report from a contactable consumer (patient). A 65-year-old female patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 08Jan2021 at single dose for COVID-19 immunization. The patient medical history was not reported. The patient's concomitant medication included amlodipine, metformin and propranolol. The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 18Dec2020 at single dose for COVID-19 immunization and experienced severe headache and diarrhea. On 13Jan2021, the patient reported that: ""my body collapsed, I had a pulmonary embolism. I had to go to the hospital in ambulance. When I was there, they find out that I have clot in my lung. I was in an intensive care for 2 days or 3 days and about 5 days in the hospital (from 13Jan2021 to 17Jan2021). I have behind my knee like a deep wide black spot and it is hard, my body did not have anything like that"". Therapeutic measures were taken as a result of event pulmonary embolism/ clot in lung and included treatment with ""some medications"", one of which ELIQUIS. The patient outcome of pulmonary embolism and ""clot in lung"" was recovered on an unspecified date and of deep wide black spot was unknown. The information on the batch number has been requested.""
COVID19 VACCINE	PFIZER\BIONTECH	1020280-1	30-39 years	5 days	Pt is a 33 y/o male who presents to the ED with c/o of left le swelling progressing over the last 4 days. Pt has no other c/o. Denies fever, cough, cp, abd pain, n/v/d. Pt has had his first COVID vaccine 1/30. Patient was noted to be tachycardic to the 120's in the ER, after 1L of normal saline still tachycardic to the 110's. Lower extremity doppler was negative for DVT, however PE protocol CTA of the chest was positive for a PE, report follows. Patient was given lovenox and flown to Medical Center for higher level of care.
COVID19 VACCINE	PFIZER\BIONTECH	1037837-1	Unknown	5 days	ultrasound revealed blood clots at right leg; Swollen ankle and foot after 5-6 days of first dose; Swollen ankle and foot after 5-6 days of first dose; This is a spontaneous report from a contactable consumer reported for herself. A 73-year-old female patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in left arm on 20Jan2021 11:00 at single dose for COVID-19 immunisation. The patient was vaccinated in nursing home/senior living facility. Medical history included high blood pressure, monitored for lymph node growth. The patient had no known allergies. Prior to vaccination, the patient was not diagnosed with COVID-19. Concomitant medication included high blood pressure medication and clonazepam. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced swollen ankle and foot on 25Jan2021 12:00 AM after 5-6 days of first dose, ultrasound revealed blood clots at right leg. Doctor ordered to take apixaban (ELIQUIS) immediately during second week. The events resulted in Doctor or other healthcare professional office/clinic visit. Since the vaccination, the patient had not been tested for COVID-19. The outcome of events was not recovered. Information on the lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1050064-1	65+ years	5 days	Resident with acute onset of SOA this AM with Sao2 of 65%. Transferred to ER with diagnosis of bilateral pulmonary embolism
COVID19 VACCINE	PFIZER\BIONTECH	1052844-1	65+ years	5 days	Pfizer-BioNTech COVID-19 Vaccine EUA: five days after vaccination patient presented to emergency department with left-sided facial droop, right gaze preference, and left hemi-paresis. Patient diagnosed with right middle cerebral artery occlusion, likely thrombotic etiology, admitted to hospital, and underwent thrombectomy and recanalization with symptom improvement. Discharged to home improved, stable, with vital signs within normal ranges two days after arrival to emergency department.

COVID19 VACCINE	PFIZER\BIONTECH	1090733-1	65+ years	5 days	The patient is a very pleasant 65 year old gentleman with a history of hypertension who presents to the hospital reporting a fever, cough, and chest pain starting two weeks ago. He states that he has had flu-like symptoms for the previous two weeks with a prominent nighttime fever and sweats. He states that he had a similar episode approximately one year ago. He reports that since Saturday he became short of breath. He states that when he goes and feeds the horses and walks back he is short of breath and needs to rest. He denies any myalgias, nausea, vomiting, diarrhea, or abdominal pain. He reports that he has chest heaviness. In the emergency department he was diagnosed with pulmonary emboli with large clot burden. He states that he has never had a blood clot. He has no family history of cancer, deep venous thrombosis, or pulmonary embolus. He denies any melena or hematochezia. He states he has not had a colonoscopy. He reports that over the past two weeks he has not been moving around much, saying that he has been largely confined to his chair due to his illness
COVID19 VACCINE	PFIZER\BIONTECH	1106640-1	65+ years	5 days	During my earlier years working in an industrial area I had inhaled asbestos which caused me to have plural thickening in my lungs. Every year since that diagnosis I have been required to annual Pulmonary (lung and heart) testing. On February 11th I had my 30th annual Pulmonary exam consisting of EKG, Stress Test, and Chest X-ray. As in the past, results were all good. On March 3rd I had my 1st Pfizer vaccination. Five days later on March 8th I collapsed, was taken to the hospital by ambulance having suffered a massive Pulmonary Embolism affecting my heart and right lung. During my 2 hour operation, Surgeons used a flexible suction tube inserted thru my groin to remove a large blood clot (embolectomy). Pieces totaling about 14cm long, 2cm wide and 1/2 cm thick. I was discharged 3 days later and instructed to take blood thinning medication probably for the rest of my life. I am now 78 years old.
COVID19 VACCINE	PFIZER\BIONTECH	1121596-1	65+ years	5 days	Bilateral pulmonary embolism; hypertension; shortness of breath; This is a spontaneous report from a contactable consumer. A 75-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number unknown) via an unspecified route of administration on 25Feb2021 at age of 75-year-old at single dose for COVID-19 immunisation. Medical history included chronic lymphocytic leukemia, stem cell transplant recipient, and prostate cancer. Known allergies: possibly penicillin. No COVID prior vaccination. The patient's concomitant medications were not reported. The patient experienced bilateral pulmonary embolism, hypertension, and shortness of breath on 02Mar2021. The events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization. It was unknown if treatment received for the events. It was unknown if COVID tested post vaccination. The outcome of the events was unknown. Information on the lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1142161-1	65+ years	5 days	DVT and pulmonary embolism
COVID19 VACCINE	PFIZER\BIONTECH	1143474-1	Unknown	5 days	blood clots in couple of toes near nails; observed swollen; This is a spontaneous report from a non-contactable consumer. A 55-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: EL3247), via an unspecified route of administration, administered in arm left on 24Feb2021 15:15 as a single dose for covid-19 immunisation . The patient has no medical history. The patient has no known allergies. The patient's concomitant medications were not reported. In Mar2021, the patient was observed with swollen and blood clots in couple of toes near nails. The events was not treated. The outcome of the events was not recovered. The patient has not had covid prior to vaccination and was not testes for Covid post vaccination. No follow-up attempts are possible. Information about Lot/Batch cannot be obtained.

COVID19 VACCINE	PFIZER\BIONTECH	1150394-1	65+ years	5 days	Two blood clots in left leg; This is a spontaneous report from a contactable consumer. A 77-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration, administered in left arm on 26Feb2021 (Batch/Lot Number: EN6203) as single dose for COVID-19 immunisation. Medical history included back disorder, ATTR amyloidosis, and allergies: caffeine from an unknown date. Concomitant medication included allopurinol (ELAVIL); meloxicam; tizanidine; tafamidis (VYNDAMAX) all taken for an unspecified indication, start and stop date were not reported. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9269), on 05Feb2021, administration time: 06:00 PM, vaccine location: Left arm for COVID-19 immunisation. The patient experienced two blood clots in left leg on 03Mar2021 23:00. Treatment for the event includes Aspirin. The event resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The patient had no COVID-19 prior vaccination. The patient was not tested for COVID-19 post vaccination. The outcome of the event was resolved on an unspecified date.
COVID19 VACCINE	PFIZER\BIONTECH	1151639-1	65+ years	5 days	Patient is a 69 y.o. male patient who originally presented to the hospital on 3/23/2021 due to shortness of breath. Patient had 1 week of shortness of breath. He starts experiencing 2 weeks of pain in edema right lower extremity. Did notice increasing dyspnea on exertion. Was noted to have bilateral PEs with evidence of RV strain on CT scan. She admitted to the ICU on heparin drip he did undergo tPA. Echocardiogram documented to be improving. Patient now baseline ambulatory in the room without oxygen stable.
COVID19 VACCINE	PFIZER\BIONTECH	1201939-1	65+ years	5 days	I was hospitalized due to severe blood clotting for four days following surgery to remove scar tissue from the urinary/prostate area and am now on blood thinner medication.
COVID19 VACCINE	PFIZER\BIONTECH	1211991-1	65+ years	5 days	Clots Ongoing
COVID19 VACCINE	PFIZER\BIONTECH	1212230-1	30-39 years	5 days	pt started having symptoms 2 days after getting the vaccine. It started with vomiting, body aches and fever and he continued to decline. He went to ER with worsening abdominal pain. He was given a CT. He was treated for diverticulitis. He was sent home with antibiotics. He did not improve and went back to same ER. He was transferred an unspecified hospital. He has septic thrombosis inferior mesenteric vein which is protruding into the junction of the portal vein and SNV. He is currently in ICU on heparin and watching him for any acute mesenteric ischemia. Blood Culture is positive for E.coli.
COVID19 VACCINE	PFIZER\BIONTECH	1213306-1	60-64 years	5 days	blood clotting in legs, lungs, resulting in hospitalization. Second clotting event resulting in stroke and hospitalization, ongoing treatment and evaluation
COVID19 VACCINE	PFIZER\BIONTECH	1218673-1	50-59 years	5 days	Wife found unconscious on kitchen floor.
COVID19 VACCINE	PFIZER\BIONTECH	1257393-1	50-59 years	5 days	5 days after I had the second dose of the Pfizer Covid vaccine, I had blood clots that caused several strokes. I have normal cholesterol, normal blood pressure, normal A1C and other diabetes measures, and my blood was tested for multiple things to identify what caused the clotting. Every single test came back within normal limits. The ONLY thing that changed was that vaccine. And it was 5 days after the second dose. The doctors cannot figure out why I had a stroke.
COVID19 VACCINE	PFIZER\BIONTECH	1261715-1	65+ years	5 days	DVT; This is a spontaneous report from a contactable consumer reporting for a patient. An 88-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration on 24Feb2021 (Batch/Lot Number: EN6200) as SINGLE DOSE for covid-19 immunisation, at 88 years old. Medical history included High blood pressure from an unknown date. No COVID prior vaccination. Not tested for COVID post vaccination. No known allergies. The patient received the first dose of BNT162B2 (Lot number e19264) on 03Feb2021 for Covid-19 immunization. Concomitant medication included simvastatin (ZOCOR); terazosin; carvedilol; ranitidine, taken for an unspecified indication, start and stop date were not reported (Other medications in two weeks). Lower right leg swelling was noted beginning approximately on 01Mar2021 without injury or pain that worsened through 04Mar2021. Patient was taken to ER on 05Mar2021 when DVT was diagnosed. Therapeutic measures were taken as a result of DVT includes XARELTO. Outcome of the event was recovering.

COVID19 VACCINE	PFIZER\BIONTECH	1265998-1	30-39 years	5 days	Blood clot in right lung; This is a spontaneous report from a contactable consumer (patient). A 33-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EN6204; Expiration date was not reported) on the right arm on 26Mar2021 (18:45) as a single dose, with route of administration unspecified, for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number and expiration date were not reported) on an unspecified date for COVID-19 immunization. On 31Mar2021, the patient had blood clot in the right lung. The event resulted into doctor or other healthcare professional office/clinical visit and emergency room/department or urgent care, and the patient was hospitalized on an unspecified date in 2021 for two days due to the event. The patient did not receive any treatment for the event. The outcome of the event, 'blood clot in the right lung', was recovered on an unspecified date in 2021 with lasting effects. The patient was not diagnosed with COVID-19 prior to vaccination, and had tested negative for COVID-19 nasal swab test on 01Apr2021.
COVID19 VACCINE	PFIZER\BIONTECH	1269723-1	50-59 years	5 days	DVT in right leg; Swelling in right leg; Discomfort in right leg while walking; This is a spontaneous report from a contactable consumer (patient). A 58-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration, administered in the left arm on 10Mar2021 at 16:30 (batch/lot number: EN6208) as a single dose for COVID-19 immunisation (wanted the protection). Medical history included deep vein thrombosis (DVT) from Jul2018 and ongoing. No family medical history relevant to the adverse events. Concomitant medication included warfarin taken for maintenance level for history of DVT from Aug2020 and ongoing. The patient experienced DVT in right leg on 02Apr2021, swelling in right leg on 15Mar2021 and discomfort in right leg while walking on 15Mar2021. The patient reported that he had a reaction to the COVID-19 vaccine and he believes that it was directly related to the COVID-19 vaccine. He reported that he has a history of blood clots in his right leg going back to 2018. He reported that his most recent DVT was in Aug2020 and he was cleared in Nov2020. He reported that he received the COVID-19 vaccine on 10Mar2021. He reported that on 15Mar2021, he started to notice his right leg swelling. He reported that he called his physician on 29Mar2021 and that his physician ordered an ultrasound. He reported that he had the ultrasound on 02Apr2021 and a deep vein thrombosis was found again. Swelling in right leg: he reported that the swelling has gone down. He reported that the reason that he mentioned that he has a history of blood clots was because of his warfarin dosage. He reported that he was first diagnosed with a deep vein thrombosis in Jul2018. He reported that he went through that cycle and that his maintenance level of warfarin was maybe 10 or 12 mg of warfarin per day. He reported that he had another deep vein thrombosis in Aug2020, and since Aug2020 he has been on 17 mg of warfarin daily. He reported that the blood level on warfarin maintenance was supposed to be between 2 and 2.5. He reported that now because of the deep vein thrombosis he experienced in Aug2020, his doctor wanted his level to be at 2.5 to 3.5. He stated that he doesn't think that at that blood level for his warfarin that he should have gotten a blood clot. He reported that something compromised or interfered with the warfarin, resulting in a deep vein thrombosis. Discomfort when walking: he reported that it feels like his leg was compressing. He reported that the discomfort seems to have gotten better. He was queried for details of warfarin prescription. He reported that the 10 or 12 mg warfarin tablets that he had been taking when the blood clot was diagnosed in Aug2020 have been consumed and he no longer has the bottle. He reported that he did not have the bottle with him for his current warfarin prescription. He reported that the warfarin was not auto-refilled by the pharmacy. He reported that the warfarin was only prescribed a week or two at a time. Investigations: he reported that since Aug2020 when the deep vein thrombosis returned, he started doing self INR tests at home. He reported that he constantly self-monitors his INR at home and his levels were consistently at 3.0 to 3.1. He reported that he monitors his INR at least once a week, sometimes twice a week depending on how he feels. He reported that sometimes his INR goes over 4 and he can feel it. He reported that his system was a little off when it feels too high so he knows how to adjust. He reported that he last checked his INR today, 15Apr2021, and that it was 4.0. He reported that he typically checks his INR on

COVID19 VACCINE	PFIZER\BIONTECH	1278552-1	Unknown	5 days	<p>Patient had bilateral pulmonary embolisms; This is a spontaneous report from a contactable physician. An elderly (also reported as 65+ years) female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 intramuscular, administered in Arm Left on 02Apr2021 (Batch/Lot Number: EN6205) as single dose for COVID-19 immunization. The patient medical history was not reported. The patient is not pregnant. The patient had no known allergies. Concomitant medication included apixaban (ELIQUIS); monascus purpureus (RED YEAST RICE); colecalciferol (VIT D3); calcium; all taken for an unspecified indication, start and stop date were not reported. The patient had bilateral pulmonary embolisms on 07Apr2021 and was hospitalized for 2 days. There are no other vaccines in four weeks, no prior vaccination and was not tested positive post vaccination. Anticoagulation therapy was given as treatment. The outcome of the event was recovering.; Sender's Comments: Considering a plausible temporal relation, a causal relationship between the reported event of Pulmonary embolism and suspect drug bnt162b2 cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Committees, and Investigators, as appropriate.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1279276-1	50-59 years	5 days	<p>big knot there and now its black and blue and it's also like ball/could be a blood clot on her hand; Headache; sickness; felt like little vomit; not having a very good appetite; feeling like sinus; feeling little nauseas; bruise on the top of her hand and then that bruise move to left part of her upper hand; This is a spontaneous report from a contactable consumer (patient) reported that a 53-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: ER8727), via an unspecified route of administration on 08Apr2021 (at the age of 53-years-old) as a single dose for covid-19 immunisation. The patient medical history included cardiovascular disease. She has had open heart surgery, a double bypass when she was 44. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 18Mar2021 (at the age of 53-years-old) for covid-19 immunisation, and experienced face got swollen and got red and she think she got wet nose right there swelling a little bit same time her face swollen. Additional medical history included anxiety and depression. Concomitant medications included acetylsalicylic acid, ascorbic acid (ASPIRIN [ACETYLSALICYLIC ACID;ASCORBIC ACID]); atorvastatin; midodrine; metoprolol; clopidogrel; ranolazine; meclizine hydrochloride (MECLIZINE HCL); hydrocortisone; glyceryl trinitrate (NITROGLYCERIN); zinc sulfate (ZINC SULPHATE); gabapentin; colecalciferol (VITAMIN D [COLECALCIFEROL]); and paracetamol (ACETAMINOPHEN); all were taken for an unspecified indication, start and stop date were not reported. Additional concomitant medications included duloxetine taken for depression and anxiety; and alprazolam (XANAX) taken for anxiety; both start and stop date were not reported. On 13Apr2021 5 days after the second vaccination, the patient experienced headache every single day with sickness and felt like little vomit and not having a very good appetite at all. She was feeling ""sinusy"" but she don't have any sinus issues and then she was feeling little nauseas and then her right hand for some reason she got bruise on the top of her hand and then that bruise move to left part of her upper hand and gotten a big knot there and now its black and blue and it's also like ball; her husband and she think that could be a blood clot on her hand. The outcome of the events was unknown.""</p>
COVID19 VACCINE	PFIZER\BIONTECH	1283410-1	65+ years	5 days	<p>Patient had a stroke on March 15, 2021 as described as a blood clot in her brain. Medical personnel were unable to correct it surgically and she passed away that evening in the hospital. Death was the final result.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1284853-1	40-49 years	5 days	I had a Stroke; Blood clot travelled to my brain; effected left side of my body; ability to speak; This is a spontaneous report from a contactable consumer (patient). A 46-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot: ER 8729), via an unspecified route of administration in left arm on 10Apr2021 (at the age of 46-years-old) as single dose for covid-19 immunisation. The vaccination facility type was a pharmacy/drug store. The patient's medical history and concomitant medications were not reported. The patient had no known allergies. The patient did not have covid prior vaccination. The patient had no other vaccine in four weeks and no other medications in two weeks. The patient had a stroke. Blood clot travelled to his brain and effected left side of his body and ability to speak on 15Apr2021 at 17:30. The events resulted to emergency room/department or urgent care, hospitalization for 3 days, life threatening illness (immediate risk of death from the event), disability or permanent damage. The patient received unspecified treatments for the event. Covid test post vaccination on 15Apr2021 with result of negative. The outcome of the events was recovering.
COVID19 VACCINE	PFIZER\BIONTECH	1294682-1	30-39 years	5 days	I had DVTs in my right calf that landed me in the ER a week after my first shot.; This is a spontaneous report from a contactable consumer (patient). A non-pregnant 33-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 1 via an unspecified route of administration, administered in left arm on 03Mar2021 at 10:45 AM (Lot number: UNKNONW), at the age of 33 years, as a single dose for COVID-19 immunization. Medical history included protein C deficiency, drug hypersensitivity to Sulfa. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within four weeks prior to the vaccination. There were no concomitant medications. The patient reported ""I had DVT's in my right calf that landed me in the emergency room (ER) a week after my first shot on 08Mar2021. Therapeutic measures were taken as a result of ""I had DVTs in my right calf that landed me in the emergency room (ER) and included blood thinning medication. The clinical outcome of DVT was recovering. It was also reported that since the vaccination, the patient had not been tested for COVID-19. Information on the lot/batch number has been requested.""
COVID19 VACCINE	JANSEN	1107565-1	18-29 years	6 days	On 3/14/21 patient started with left flank pain that radiated to left shoulder and increased pain while taking a deep breath. Mother called on 3/16/21 and patient was seen in primary clinic for issue. She had labs and xray done. Xray showed possible mild opacity in left lower lobe and to do ct scan. Ct pe study done same day showing bilateral lower lung pulmonary emboli and lower lung patchy infiltrates. Patients pain progressively got worsened and was seen in the er to be transferred to outgoing facility for care.
COVID19 VACCINE	JANSEN	1114806-1	40-49 years	6 days	Diagnosis: Cortical vein thrombosis, massive intracerebral hemorrhage with tentorial herniation, thrombocytopenia. Clinical Presentation and Course: 1 week after receiving Janssen COVID19 vaccination, patient developed gradually worsening headache. On March 17th, patient presented to Hospital with dry heaving, sudden worsening of headache and L sided weakness. Evaluation with head CT revealed a large R temporoparietal intraparenchymal hemorrhage with 1.3cm midline shift. She ended up getting intubated for worsening mental status. On evaluation at arrival in Medical Center, she was noted to have extensor posturing. Repeat imaging revealed worsening midline shift to 1.6cm. CTA showed cortical vein thrombosis involving the right transverse and sigmoid sinus with tentorial herniation. Patient developed brain herniation and brain death was pronounced on March 18th, 2021.
COVID19 VACCINE	JANSEN	1182133-1	18-29 years	6 days	She received the J and J vaccine on 3/19/21 at STM. She presented to Med center with a ""viral syndrome"" including fevers, rigors, muscle pain and SOB. She received a Z pack. Fever persisted for 1 day after ER visit but she continued to feel badly. The following day, 3/27 she was awakened with severe R>L jaw pain, post HA with standing, pain in the cartilage on the tip of her nose and SOB. SOB resolved by 3/31. HAS persisted as did jaw pain and pain behind her eyes. ON 3/30 she noted increasing bruising and periorbital petechiae which continued through 4/5 when she sought help from Dr , her PcP. When she saw DR she was noted to have bilateral leg swelling R>>L . She had labs and a Doppler US which we are trying to locate. She had a syncopal spell on 4/6 and was brought to ER at STM where she was diagnosed with sagittal vein thrombosis, RLE DVT and thrombocytopenia.""
COVID19 VACCINE	JANSEN	1195850-1	65+ years	6 days	Death by clot

COVID19 VACCINE	JANSSEN	1201310-1	40-49 years	6 days	I have a history of untreated fibroids that were diagnosed in December 2019. Because the coronavirus pandemic began in February 2020, elective surgeries were not allowed in my state. My bleeding and blood clots were caused by the fibroids during menstruation. On March 20, 2021, I received the Johnson & Johnson 1-shot COVID vaccine. By March 26th, the blood clots that were coming out of my body were enormous. They had NEVER been that large. Being concerned, I immediately saw my doctor as soon as my period ended. Today, I learned the J&J vaccine has been paused due to blood clots. I believe that my blood clots became so large because I was given this particular vaccine. WOMEN SHOULD BE ADVISED THAT IF THEY HAVE BLOOD CLOT CAUSING FIBROIDS, DO NOT TAKE THE JOHNSON & JOHNSON COVID-19 VACCINE.
COVID19 VACCINE	JANSSEN	1201372-1	65+ years	6 days	Resident c/o L arm pain on 4/7/2021 approx 2300. Resident transferred to ED for evaluation, CT abnormalities, transfer to higher level of care, clot manually removed on 4/8/2021, resident returned to nursing facility on 4/12/2021 without complications
COVID19 VACCINE	JANSSEN	1201494-1	65+ years	6 days	Suprafacial blood clot in lower left leg. Pt contacted PCP, told to take 2 X 81mg aspirin for two weeks. Symptoms have resolved as of 4/13/21 when first reported to pharmacy.
COVID19 VACCINE	JANSSEN	1202482-1	40-49 years	6 days	blood clots
COVID19 VACCINE	JANSSEN	1203630-1	50-59 years	6 days	Patient developed a Pulmonary embolism
COVID19 VACCINE	JANSSEN	1204671-1	40-49 years	6 days	Janssen COVID-19 Vaccine EUA: twelve days after vaccination patient presents to emergency department with a headache that started seven days prior to arrival. Patient describes headache as different than normal headaches: worse with movement and episodes of dizziness. Patient also has rash/redness on right cheek of the face. Vital signs within normal ranges except blood pressure 141/96 mmHg. Patient admitted to hospital for further testing and management.
COVID19 VACCINE	JANSSEN	1204878-1	30-39 years	6 days	Right lower extremity DVT (popliteal vein)
COVID19 VACCINE	JANSSEN	1205012-1	30-39 years	6 days	Lower leg pain, confirmed clot about 4 inches long via an ultrasound on 4/9
COVID19 VACCINE	JANSSEN	1205385-1	40-49 years	6 days	Long period with heavy bleeding with blood clots. This has never happened before in my entire life.
COVID19 VACCINE	JANSSEN	1205729-1	65+ years	6 days	My husband is still in hospital trying to recover. He had bad headaches that then led to seizures and confusion ,blood clots, and has been hospitalized since. He's literally fighting for his life and tomorrow Wednesday April 14 th he will be transferred to a rehabilitation center.
COVID19 VACCINE	JANSSEN	1206413-1	50-59 years	6 days	left leg pain and swelling, redness, increased warmth worsening over 1 week
COVID19 VACCINE	JANSSEN	1207392-1	50-59 years	6 days	Acute bilateral PE and acute DVT
COVID19 VACCINE	JANSSEN	1207440-1	65+ years	6 days	Massive heart attack due to blood clot. Heart Cath putting in a stint with over night stay in hospital
COVID19 VACCINE	JANSSEN	1209363-1	30-39 years	6 days	Since vaccination the patient has had a severe headache (unlike her typical episodic migraine), and then developed left hemibody anesthesia, LUE drift. CTA demonstrated Right ICA dissection (of unknown duration) with string sign, acute right MCA artery to artery sub-occlusive embolus, MRI shows right MCA ischemic infarct.
COVID19 VACCINE	JANSSEN	1211589-1	40-49 years	6 days	Dx: Acute DVT of the left posterior tibial vein (distal to popliteal) shown on US, opted for repeat CBC next AM to confirm platelet count stability and US in 1 week to assess DVT progression vs stability Symptoms: Headache, nausea, myalgia, shortness of breath, forgetfulness, leg pain starting from bilateral feet cramping
COVID19 VACCINE	JANSSEN	1212978-1	30-39 years	6 days	Pt states that on Monday she noticed that she couldn't put pressure on her leg to walk. (04-12-21) Pt called and made an appointment on 04-13-21 and saw her PCP. Ultrasound was ordered and was dx with near occlusive vein thrombosis in the distal right femoral vein. Pt was prescribed Lovenox 100mg to take now and was also prescribed eliquis 5 mg twice daily, and acetaminophen-codeine to help with the pain.
COVID19 VACCINE	JANSSEN	1214577-1	40-49 years	6 days	RLE thrombosis of greater saphenous vein
COVID19 VACCINE	JANSSEN	1219069-1	40-49 years	6 days	Patient has been admitted to the hospital on 4/15/21 with a right sigmoid sinus/jugular vein thrombus.
COVID19 VACCINE	JANSSEN	1225176-1	30-39 years	6 days	Pulmonary embolism
COVID19 VACCINE	JANSSEN	1225184-1	50-59 years	6 days	On April 7th received Janssen COVID vaccine at pharmacy. On April 13 started developing shortness of breath and dizziness/light headed. Had knee surgery at hospital the 14th on right knee to remove cyst (scheduled surgery). On 15th still short of breath and felt like had cold. Worsening SOB on 16th. On 17 was SOB walking from bathroom. Talked to daughter on phone and she said to go to ER. Went to ER about 8pm and Was diagnosed with bilateral blood clots in lungs and admitted to step down on heparin drip. Getting Echo TEE on Monday 19th and bilateral leg ultrasounds today on 18th

COVID19 VACCINE	JANSSEN	1225381-1	50-59 years	6 days	SOB/wheezing began 7 days after Janssen Covid vaccine. Patient found to have a PE and COPD exacerbation.
COVID19 VACCINE	JANSSEN	1229299-1	18-29 years	6 days	Blood Clot diagnosed at Hospital.
COVID19 VACCINE	JANSSEN	1229944-1	18-29 years	6 days	21 y.o. male with no significant PMHx who received the Johnson and Johnson vaccine 4/10/21 found to have extensive LLE DVT (extending above inguinal ligament). Pt was transferred to OSF for catheter directed thrombolysis. He was given 10 mg Eliquis prior to transfer. Pt reports acute onset of LLE pain the evening of 4/16 with progressive pain over the weekend and development of LLE edema/redness 4/18. Left leg mildly more edematous than right. Foot pink/warm, sensorimotor intact. No skin discoloration. Pt denies recent surgery, prolonged immobility or known family history of clotting disorders.
COVID19 VACCINE	JANSSEN	1230405-1	60-64 years	6 days	Six days after receiving the Johnson & Johnson/Janssen vaccine, the patient complained about strong pain in the right arm (same as vaccination arm). She went to the ER on the 7th day after receiving the vaccination and after doing EKG, ultrasound, and CT scan, they found multiple blood clots in her right arm where she receive the vaccine.
COVID19 VACCINE	JANSSEN	1230785-1	65+ years	6 days	Acute respiratory failure- bilateral pulmonary emboli. Acute renal injury. New onset of atrial fibrillation. Patient in ICU intubation occurred on 4.18.2021
COVID19 VACCINE	JANSSEN	1234046-1	65+ years	6 days	Received a Janssen vaccination on 4/7/21 from a home visiting nurse from the County Health Department. On approximately 4/13/21, the family noticed slight signs of an issue, with patient slumping towards the right, and showing some signs of weakness on right side of body. Family contacted the PCP, who advised to take her to the ED. Family was hesitant to do that because patient had been bedridden for past few years. She seemed to improve somewhat on 4/15/21. Then the morning of 4/16/21, the family found her on the floor of her bedroom. She appeared to have had a moderate to severe stroke. Right side of body paralyzed, cannot speak. Uncertain whether mental faculties further deteriorated. PCP ordered a hospice facility for care. Stroke likely caused by blood clot but unsure if related to JJ vaccine. She has not been evaluated in person by her health care providers.

COVID19 VACCINE	JANSEN	1234152-1	40-49 years	6 days	Pt. had (what we think) a small seizure on Thursday, March 18th and then again on Saturday, March 20th. On Sunday, March 21st, 911 had to be called as his seizure did not end. He had a grand male. He was seizing for several hours. At the time this was all occurring he has been on anti seizure meds for a few years (Divalproex 1000 mg am and 1000 mgs pm daily). He passed 1 week later, March 28 at approx 6:45pm at the Clinic. I am unable to get any information on his medical report for that week. Statement from his Neurologists is on second page. Additional information for Item 18: Statement: 47 year old gentleman who passed away on March 28 from aspiration pneumonia secondary to status epilepticus and on a history of multiple sclerosis / additional leukoencephalopathy of unknown etiology (both treated with rituximab), prior seizures (on valproic acid) and pulmonary embolism (on apixaban). The key reason for reaching out is in light of the announcement about the side effects of the Johnson & Johnson vaccine specifically cerebral venous sinus thrombosis. While he had a known history of seizures, he had no clear trigger for these seizures; including that his valproic acid level was therapeutic (83.0 mcg/mL) at time of presentation. He had, however, received the Johnson & Johnson vaccine on March 12 before having what in hindsight appeared to be repeated seizures between March 18-21; he had a more significant one on March 21 that hospitalized him. This time frame appears consistent with the reported cases of central venous sinus thrombosis associated with the Johnson & Johnson vaccine. Equally, he was taking apixaban at that point in time and his PLT (173) / INR (1.1) / PTT (36.6) at time of presentation were all normal and stable. He did have an elevated ProBNP (552.0) at presentation; nasopharyngeal swab was negative for COVID / Influenza A/B / RSV and non-contrast head CT did not show any clear new abnormalities. His only D-dimer was obtained on March 23 and was 226. He did not have a CT angiogram or venogram. Overall the link between the vaccine and pt. seizures is not definite. At the same time, the similarity with the reported cases has led to me wanting to report it in case of the possible link. If you require further information then please don't hesitate to email me Pt. med list at the time of this incident Modifinil - 100 mg/1per day/AM Sertraline - 100 mg/1per day/AM Vitamin D3 - 50 mg/1per day/AM Divalproex - 500 mg/2per day/AM Eliquis - 5 mg/1per day/AM Furoseminde - 20 mg/1per day/AM Metoprolol - 100 mg/1per day/AM Lisinopril - 10 mg/1per day/AM Divalproex - 500 mg/2per day/PM Eliquis - 5 mg/1per day/PM Metoprolol - 100 mg/1per day/PM Melatonin - 5 mg/1per day/PM Quetiapine - 50 mg/3per day/PM
COVID19 VACCINE	JANSEN	1238239-1	40-49 years	6 days	DVT left leg requiring surgical procedure 04/13/2021. Went to ED on 4/12/2021 with severe leg pain, warmth of area.
COVID19 VACCINE	JANSEN	1238583-1	65+ years	6 days	States she developed leg pain 6 days after shot and didn't think it was anything to worry about until she saw the J&J blood dot news and decided to get checked. Had appt and ultrasound on 4/19/2021 with NP. Found to have two non-occlusive, small blood clots in the right leg.
COVID19 VACCINE	JANSEN	1238647-1	65+ years	6 days	Large DVT left lower extremity
COVID19 VACCINE	JANSEN	1241787-1	50-59 years	6 days	Intermittent shortness of breath a few days prior to presenting on 4/22/2021. Patient also c/o bilateral lower leg pain, hand pain, and difficulty sleeping. Evaluation by CTA revealed Pulmonary Emboli.
COVID19 VACCINE	JANSEN	1247460-1	40-49 years	6 days	Left calf and thigh pain and swelling on the 6th day following vaccine which continued intermittently for a total of 12 days. I was seen at an urgent care, a left leg ultrasound was completed and I was diagnosed with deep venous thrombosis. I was prescribed Xarelto.
COVID19 VACCINE	JANSEN	1251851-1	50-59 years	6 days	Progressive headache, leading to ER admission, diagnosis of Left sigmoid sinus thrombosis accompanied by severe thrombocytopenia. Diagnosis confirmed as vaccine-induced immune thrombocytopenia and thrombosis (VITT)/vaccine-associated thrombosis and thrombocytopenia (VATT).
COVID19 VACCINE	JANSEN	1256081-1	50-59 years	6 days	April 14, my sister was transported to hospital feeling faint and numbness in her left leg. As a result, she was admitted and treated for: ? blood pressure readings as low as 82/43, 76/50 while standing ? blood clots on her heart that traveled to her brain that were causing multiple mini strokes ? 95% blockage in her right heart vessel which required a stent ? 50% and 60% blockage in other chambers that will require attention She was given heparin and then switched to a different blood thinner to dissolve the clots. she was discharged on April 23rd with instructions to followup with her cardiologist and neurologist.

COVID19 VACCINE	JANSSEN	1256268-1	40-49 years	6 days	Iliac vein thrombosis pt started with right lower quadrant abdominal pain six days after vaccine. Persistent pain since then leading to hospital stay and diagnosis on imaging of right iliac vein thrombosis. no prior history of DVT, no family history of DVT, no inciting event/travel/change in activity level/surgery/illness
COVID19 VACCINE	JANSSEN	1256680-1	50-59 years	6 days	Patient presented post-seizure. Reported 1 week of headache prior to presentation. Found to have cerebral venous sinus thrombosis, small areas of hemorrhage in the right frontal lobe, and bilateral pulmonary emboli, as well as thrombocytopenia (previously had normal platelet count). Per MD ""Clinical picture is entirely consistent with VITT. See no other obvious explanation for this constellation of clinical findings. ""
COVID19 VACCINE	JANSSEN	1280744-1	40-49 years	6 days	12 hours after injection, experienced normal side effects (e.g., muscle aches, chills, headache, fatigue) Within 1 week of receiving the vaccine, I began to experience blurriness in my left eye. After conferring with my primary care facility, it was recommended that I see an ophthalmologist. Confirmed that I had a Branch Retinal Vein Occlusion (BRVO) and recommended I meet with a retinal specialist. Dr. confirmed the BRVO was caused by a blood clot and commenced treatment via eye injection. I then met with my primary physician to discuss the situation. He recommend further tests to determine whether I had other clotting. In addition to blood work, he order MRIs of my brain, head and neck region and also recommended that I meet with a thrombosis specialist. I met with a Dr. who ordered additional blood work for additional testing. All tests performed to determine if I had additional clotting have come back negative.
COVID19 VACCINE	JANSSEN	1282452-1	30-39 years	6 days	Bilateral pulmonary embolism
COVID19 VACCINE	JANSSEN	1284268-1	18-29 years	6 days	Was was pain in calf area and having a hard time breathing and very tired.. went to doctor on 4/20/2021 Doctors Diagnosed with Pulmonary Embolism
COVID19 VACCINE	MODERNA	0933686-1	60-64 years	6 days	rib pain/shortness breath/Pulmonary Embolus and viral pneumonia Narrative: Development of symptoms beyond the 48-72 window. Tested at time of ER visit Negative for Covid. Repeated Covid NP swab on 01/05/2021. Was not hospitalized overnight discharge home on oral anticoagulant medications.
COVID19 VACCINE	MODERNA	0942005-1	50-59 years	6 days	swelling in neck and down chest blood clots enlarged lymph nodes
COVID19 VACCINE	MODERNA	0946819-1	30-39 years	6 days	Patient developed headache and nausea on 1-11-2021. She was hospitalized on 1-14-2021 at Hospital. Found to have dural sinus thrombosis of the superior sagittal and right transverse/sigmoid sinus on MRV brain. Currently admitted to ICU at Hospital, getting injectable blood thinners. Neurology and hematology have been consulted.
COVID19 VACCINE	MODERNA	1019577-1	65+ years	6 days	Pt awoke on 2/8 feeling tired and weak. On 2/9 patient developed fever to 102 and shortness of breath and vomiting. Was seen in ER and admitted for presumed UTI as well as small PE.
COVID19 VACCINE	MODERNA	1019785-1	40-49 years	6 days	1 week after the first dose patient started to have her period. The period consisted of heavy clots and would go through 6-8 pads /day. Period lasted 3 weeks and went to see GYN and they prescribed Provera, which helped stop the bleeding.

COVID19 VACCINE	MODERNA	1026921-1	65+ years	6 days	<p>HISTORY OF PRESENT ILLNESS: Pleasant 78-year-old female with history of lung cancer with remote partial pneumonectomy, some element of COPD and chronic respiratory failure on home oxygen therapy. She presents with worsening shortness of breath, which started rather abruptly the day prior to presentation. On arrival to the ED she was mildly tachypneic and slightly tachycardic and appeared to be in mild respiratory distress. Her O2 had been titrated to 4 L/m nasal cannula in order to sustain SaO2 values in the 90% or above range. Patient also noted to have pallor. No hematemesis, melena, hematochezia, abdominal pain, fever, cough or known exposure to COVID. Patient reports having received her first COVID vaccination just over one 1 week ago. A hypochromic microcytic anemia, progressive, was noted with a hemoglobin of 7.4 g/dL. Patient reported that she was up-to-date on EGD and colonoscopy within the past year without findings of acute pathology or bleeding. A CTA of the chest was conducted with findings of bilateral pulmonary emboli. She denies lower extremity swelling, pain or tenderness. Patient placed in observation in order to provide palliative blood replacement therapy and commence with anticoagulation for venous thromboembolism.</p> <p>DISCHARGE SUMMARY/OBSERVATION COURSE: Uneventful observation course for this pleasant 78-year-old female who presented with somewhat sudden worsening of her chronic shortness of breath and was found to have CTA evidence of bilateral pulmonary emboli. This in the setting of a progressive iron deficiency anemia without evidence of active clinical gastrointestinal bleeding. The patient received 2 units of packed red blood cells in a palliative fashion for her presenting hemoglobin of 7.4 g/dL. Posttransfusion hemoglobin was 10.1 g/dL. Concurrently, she was placed on weight-based low molecular weight heparin for full anticoagulation. I examined the patient on the morning of February 12 and found her to be nondistressed. Her SaO2 value was 96% on 4 L/m nasal cannula O2. Recall that her baseline flow rate historically had been 2 L/m his cannula. Etiology of the patient's thromboembolism uncertain. She had no clinical findings of unilateral or bilateral lower extremity swelling or tenderness. Patient noted to be a survivor of both breast and lung cancers but without known evidence of active persistent malignancy. Of interest, she had received a COVID-19 vaccine just over one week prior to presentation. I contacted pharmacy in this regard and encouraged him to report possible adverse event via VAERS. I recommended a course of rivaroxaban and provided a prescription with a VTE dosing schedule. Patient was advised to followup with Dr in 10 days. M.D., Hospital Medicine MD Feb 12, 2021 08:40</p>
COVID19 VACCINE	MODERNA	1046684-1	40-49 years	6 days	<p>L arm pain, HA, body aches/chills starting 12/29/2020. Chest pain, SOB, cough, fevers starting 1/3/2021. Hemoptysis 1/7/2021 with worsening SOB and positional cough. Multiple PEs found on chest CT 1/10/2021 and hospitalized on heparin drip for &gt;24hrs. DVT found on lower leg US 1/10/2021. Remain on DOAC for anticoagulation.</p>
COVID19 VACCINE	MODERNA	1056972-1	65+ years	6 days	<p>5-6 days after receiving first Moderna covid vaccine pt. began not feeling well. On 02/10/2021 she saw a provider in an office for eval of abdominal pain and diarrhea and sent home. On 02/15/2021 she presented to a local ED with continuing symptoms, transferred to Medical Center, She is currently an inpatient there with a diagnosis of multiple blood clots in abdomen and brain and antiphospholipid syndrome.</p>

COVID19 VACCINE	MODERNA	1073173-1	65+ years	6 days	Moderna COVID-19 Vaccine EUA 2/27/21: Pt received 1st Moderna vaccine 2/4/2021. She states that her symptoms 1st started out as a slight postnasal drip, which turned into a hoarse voice with a cough, which turned into a head cold, which has turned in due shortness of breath, diarrhea, and cough with associated chills. After 17 days of cold-like symptoms, pt was tested on 2/26 for COVID and tested positive. 2/27, pt worsened and presented to ED. Upon arrival to the emergency department, the patient's temperature is 100.2 F, heart rate 96, respiratory rate 24, saturating 84% on room air with blood pressure 164/84. The patient's laboratory studies were significant for BUN 17, CR 1.47, lactate 2.2, D-dimer 6.79, and phosphorus 2.2. The patient's chest x-ray showed no acute findings. CT chest showed extensive acute bilateral pulmonary emboli involving most of the lobar and segmental branches, right greater than left with no saddle embolus. Findings borderline for right heart strain, correlate with echocardiogram. Peripheral ground-glass airspace opacities consistent with atypical/viral pneumonitis. Reactive mediastinal and hilar lymphadenopathy. EKG showed normal sinus rhythm, heart rate 93 with inferior infarct-age undetermined. The patient was administered 1 L IV NS, ceftriaxone 1 g IV, azithromycin 500 mg IV, and heparin IV bolus and drip for PE indication. Remdesivir started. 2/28/21: Pt on 3 L oxygen. Azithromycin, ceftriaxone, remdesivir continued. Vancomycin started. 3/1/21: 1 L oxygen via nasal cannula. Small, nonproductive cough. Pt complains of SOB. 3/2/21: 1/2 blood cultures from 2/27 positive for CoNS. Vancomycin discontinued. Pt feeling much better. Still on 1 L oxygen via nasal cannula. More alert. 3/3: 5 day remdesivir course and azithromycin, ceftriaxone course completed. Patient weaned off oxygen. Pt discharged home with oxygen as a precaution. Pt also enrolled in COVID Safe At Home telehealth program.
COVID19 VACCINE	MODERNA	1073807-1	65+ years	6 days	blood clots on lungs 2 days in hospital on blood thinner for the last 10 days
COVID19 VACCINE	MODERNA	1093451-1	40-49 years	6 days	Acute Pulmonary Embolism with lung infarct
COVID19 VACCINE	MODERNA	1102151-1	40-49 years	6 days	Developed R calf pain on 1/16/21, progressively worsening over 3-4 weeks. Diagnosed with R posterior tibial DVT on 2/6/21 and started on apixaban.
COVID19 VACCINE	MODERNA	1107187-1	65+ years	6 days	Blood clots on her legs; Blood clots on her lungs; A spontaneous report was received from a consumer concerning 89-year-old, female patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and who experienced blood clots on legs and lungs. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On 05 Feb 2021, approximately 7 days prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number not provided) via an unknown route in the right arm for prophylaxis of COVID-19 infection. On 11 Feb 2021, the patient was hospitalized for blood clots on legs and lungs for 7 days and was discharged on 17 Feb 2021. Treatment include unknown injections. Action taken with mRNA-1273 in response to the event was not provided. The outcome of the event was not reported.; Reporter's Comments: Very limited information regarding this events has been provided at this time. Further information has been requested
COVID19 VACCINE	MODERNA	1126589-1	65+ years	6 days	called received from the patients daughter that her father was admitted to the hospital with a PE 5 days after getting COVID booster. Daughter requested report be submitted as a side affect of the vaccine.
COVID19 VACCINE	MODERNA	1138686-1	60-64 years	6 days	Pt developed a RT Leg DVT Deep Vein Thrombosis and Pulmonary embolus. Started having symptoms of dyspnea, low oxygen saturations in the 80s and RT pleuritic chest pains one week after getting the shot. He had never had a DVT or PE before. Was seen in Emergency on 03-23-2021. He was admitted on 02-23-2021. Started on anticoagulation and went to the cath lab to have intraarterial administration of TPA in pulmonary arteries.
COVID19 VACCINE	MODERNA	1157841-1	65+ years	6 days	a week after injection she gained 10 lb water weight, then over the next 2 weeks an additional 20 lb of water weight. She had decrease in activity, anorexia, and was found to have multiple bilateral pulmonary emboli.

COVID19 VACCINE	MODERNA	1159908-1	60-64 years	6 days	She got her vaccine and had no reactions at all. On 3/12/21 she was in her car and started having stabbing pain in the left side of her chest under the rib. She thought it was gas pains and dismissed it, and then it started radiating towards the front and the stomach. On 3/16/21 she went to the ER and they did a CT scan that showed that she had a blood clot on her spleen. With that they gave her the diagnosis of idiopathic splenic infarction. She was then sent by ambulance to another hospital to be admitted in case she was needing surgery. She was given heparin and on that for 2 1/2 days. They determined that 60% of her spleen is dead, blood supply cut off to it, and the other 40% is nonfunctional. On 3/19/21 they gave her vaccines of Prevnar 13, HIB, meningococcal, meningococcal B, and a flu vaccine. She was discharged on the 3/20/21 with Plavix. She saw her regular doctor yesterday and he diagnosed her with functional asplenia and to continue the Plavix. She is no longer having any symptoms after dissolving the blood clot.
COVID19 VACCINE	MODERNA	1163634-1	65+ years	6 days	patient with abdominal pain, diarrhea, and PORTAL vein thrombosis
COVID19 VACCINE	MODERNA	1182162-1	65+ years	6 days	Bilateral pulmonary emboli, pt admitted, treated, discharged on blood thinners
COVID19 VACCINE	MODERNA	1184977-1	65+ years	6 days	3/14/2021 Tightness in chest, attributed to physical work outside, 3/15 still felt tightness, 3/16 getting winded and went to the ER around 5:30pm, they took blood and ran test EKG, X-ray and ECHO complete with TTCV, ultrasound of chest, and test showed multiple blood clots in both lungs; by this time he was having trouble breathing and was admitted because of the blood clots. He was given Heparin and Vicodin through IV, on 3/17 they ran more test to see where blood clots came from and where they came from but nothing was found in legs. he was in a lot of pain Wednesday and he was sent home on 3/19.
COVID19 VACCINE	MODERNA	1196323-1	30-39 years	6 days	Patient symptoms of chills, headache, and body aches began on Sunday 3/28, 6 days after vaccination. One day later, on 3/29, patient started experiencing pain in the right armpit, the same shoulder where the vaccine was received. That pain built up until Wednesday 3/31, when the arm was very swollen, purple, and rapidly losing sensation. The patient went to the ER. In the ER, via ultrasound, the patient was diagnosed with deep vein thrombosis of the right subclavian and axillary veins. From 4/1 to 4/2 the patient underwent an interventional radiology procedure, thrombolysis, using tPA directed by catheter to the site of the 12 cm long clot. On 4/2, it was determined that the flow was not restored to the vein, and the radiologist informed the patient that right first rib removal would be necessary. On 4/9, right first rib resection surgery was performed to alleviate pressure on the subclavian vein. Patient is currently recovering on the blood thinner Eliquis. Additional procedures for thromboectomy and angioplasty will follow in approximately two weeks to clear the subclavian and axillary veins.
COVID19 VACCINE	MODERNA	1199272-1	18-29 years	6 days	multiple bilateral PE with syncope
COVID19 VACCINE	MODERNA	1201899-1	60-64 years	6 days	Had systems of fatigue and chest pain. Went to hospital of 4/12/2021. Learned that had blood clots in lungs that I previously did not
COVID19 VACCINE	MODERNA	1203403-1	65+ years	6 days	Started wheezing on or about 3/23/2021; PCP prescribed Albuterol inhaler 3/25; SOB and wheezing worsened daily; 4/4/2021 was unresponsive 911 called and taken to ER with pulse ox of 58 and multiple bilateral PE noted on CT scan.
COVID19 VACCINE	MODERNA	1204581-1	65+ years	6 days	Pt presented to clinic with fatigue, SOB, general body aches on 3/22--treated for pneumonia, recheck on 3/24 found PE on CT. Admitted to hospital
COVID19 VACCINE	MODERNA	1214199-1	40-49 years	6 days	Patient reports around 5 days after receiving Moderna vaccine he experienced fever, diarrhea, n/v and SOB. Pt presented 4/07/21 to LGH ED with unremarkable blood work and negative chest x-ray, Covid negative- Pt discharged. 4/12/21 pt represented to LGH ED for some concerns and worsening sob with talking and walking and found to have PE and pneumonia

COVID19 VACCINE	MODERNA	1245398-1	30-39 years	6 days	DVT; armpit turned purple with no sensation; armpit turned purple with no sensation; excruciating pain; axillary swelling in the right arm pit; body aches; headache; chills; brain fog; lightheadedness; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEEP VEIN THROMBOSIS (DVT), SKIN DISCOLOURATION (armpit turned purple with no sensation) and SENSORY LOSS (armpit turned purple with no sensation) in a 32-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 003B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. Concomitant products included APIXABAN (ELIQUIS), OXYCODONE HYDROCHLORIDE, OXYCODONE TEREPHTHALATE, PARACETAMOL (PERCOCET [OXYCODONE HYDROCHLORIDE;OXYCODONE TEREPHTHALATE;PARACETAMOL]), PARACETAMOL (TYLENOL), OXYCODONE, DOCUSATE SODIUM (COLACE) and HYDROCODONE BITARTRATE, PARACETAMOL (NORCO) for an unknown indication. On 22-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 28-Mar-2021, the patient experienced FEELING ABNORMAL (brain fog), DIZZINESS (lightheadedness), MYALGIA (body aches), HEADACHE (headache) and CHILLS (chills). On 29-Mar-2021, the patient experienced SWELLING (axillary swelling in the right arm pit). On 31-Mar-2021, the patient experienced DEEP VEIN THROMBOSIS (DVT) (seriousness criteria hospitalization and medically significant), SKIN DISCOLOURATION (armpit turned purple with no sensation) (seriousness criterion hospitalization) and SENSORY LOSS (armpit turned purple with no sensation) (seriousness criterion hospitalization). On 02-Apr-2021, the patient experienced PAIN (excruciating pain). On 30-Mar-2021, SWELLING (axillary swelling in the right arm pit) had resolved. At the time of the report, DEEP VEIN THROMBOSIS (DVT), SKIN DISCOLOURATION (armpit turned purple with no sensation), SENSORY LOSS (armpit turned purple with no sensation), FEELING ABNORMAL (brain fog), DIZZINESS (lightheadedness), PAIN (excruciating pain), MYALGIA (body aches), HEADACHE (headache) and CHILLS (chills) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment medication - Eliquis
COVID19 VACCINE	PFIZER\BIONTECH	0989466-1	40-49 years	6 days	Deep vein thrombosis right gastrocnemius vein and superficial venous thrombosis in right small saphenous vein diagnosed January 15, 2021. Symptoms began with acute onset right lower extremity calf pain and swelling on January 14, 2021. Treatment with Xarelto began January 15, 2021.
COVID19 VACCINE	PFIZER\BIONTECH	1031884-1	65+ years	6 days	7 days post COVID #1 vaccine, onset of bilateral leg claudication (1/31/21). Subsequently dx'd with acute bilateral arterial clots in both legs requiring thrombolysis, bilateral popliteal/artery thromboembolectomy, heparin. Acute clot per vascular surgeon. Surgery performed 2/12/21.
COVID19 VACCINE	PFIZER\BIONTECH	1044102-1	65+ years	6 days	Shortness of Breath causes by multiple large blood clots, put on blood thinners, seems to be fine, but has follow up appointment in March
COVID19 VACCINE	PFIZER\BIONTECH	1045749-1	30-39 years	6 days	Soreness in the back started on 2/5/2021 and eventually moved to the abdominal area on 2/12/2021. Went to the doctor and got a CT scan and found an Acute right common iliac vein and infrarenal IVC thrombus. Many blood tests were run and no common factors were located to cause the thrombus.
COVID19 VACCINE	PFIZER\BIONTECH	1122738-1	60-64 years	6 days	blood clot formed in left arm; This is a spontaneous report from a contactable consumer (patient). A 62-year-old female patient, not pregnant at time of vaccination, received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot Number: EN6198), via an unspecified route of administration, on right Arm on 27Feb2021 0100, SINGLE DOSE for covid-19 immunisation. Medical history included Diabetic, High blood pressure, both from an unknown date. Concomitant medications included glipizide, metformin, fenofibrate. The patient previously took sumatriptan succinate (IMITREX) and experienced drug allergy. After vaccination 6 days later (05Mar2021) a blood clot formed in left arm. Shot was given in right arm. Hospitalization followed and now on blood thinners. AE resulted in: Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event). The patient was hospitalized for 2 days. The outcome of the event was not recovered. Eliquis was given as treatment for the event. No covid prior vaccination. Not covid tested post vaccination.

COVID19 VACCINE	PFIZER\BIONTECH	1123063-1	50-59 years	6 days	I started having exertional chest pain and dyspnea on 2/11/2021. I had a negative stress ECHO on 2/16/2021. Symptoms persisted and suddenly worsened on 3/9/2021 requiring an emergency cardiac cath and cardiac stents in my circumflex and LAD arteries. The cardiologist described their appearance as soft and more like clot/thrombosis than atherosclerotic plaque. There was an existing atherosclerotic plaque in my LAD that was unchanged from prior imaging studies going back to 2012. Therefore, this event did not look like progressive atherosclerosis; but instead appeared to be the sudden formation of clot/thrombosis in 2 of my coronary arteries shortly after the second dose of the Pfizer covid vaccine.
COVID19 VACCINE	PFIZER\BIONTECH	1138603-1	65+ years	6 days	Experienced a CVST
COVID19 VACCINE	PFIZER\BIONTECH	1139742-1	50-59 years	6 days	Extensive dural venous sinus thrombosis, SAH, acute ischemic thalamic infarct. Headache, lethargy, diplopia, right arm weakness
COVID19 VACCINE	PFIZER\BIONTECH	1153560-1	65+ years	6 days	Right lower extremity DVT; Bilateral PE; Severe fatigue; This is a spontaneous report from a contactable physician. A 71-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot number: EL9269) via an unspecified route of administration on 25Feb2021 at a single dose for COVID-19 immunization. Medical history included Allergies: adhesive, CT scan dye & flu shot. Concomitant medication included rosuvastatin. The patient previously received first dose of BNT162B2 on an unknown date for COVID-19 immunization. The patient also previously took Demerol, guaifenesin;phenylephrine hydrochloride (ENTEX), epinephrine, amoxicillin;clavulanic acid (AUGMENTIN) and experienced allergies. On 03Mar2021 17:15 the patient experienced severe fatigue, right lower extremity DVT, Bilateral PE. Events were considered serious, due to hospitalization for 1 day and life threatening. Treatment was received for the adverse event which included apixaban (ELIQUIS). The events resulted to a doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, patient has been tested for COVID-19 with unknown result on an unknown date. Patient was not pregnant. The facility where the vaccine was administered was in a hospital. Outcome of the events was recovering. Follow up attempts needed. Further information is expected.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1168233-1	30-39 years	6 days	Fever 103 3/27, stomach pain, vomiting, diarrhea, headache, chest pain, SOB Hospital 3/29, critically low potassium, D-Dimer elevated, chest CT clear, admitted 3/30 HIDA scan, gallbladder removed 3/31 woke with vision issues, seeing multiples of things, slanted hallways, can't stay awake 4/1 CT and MRI of brain show venous blood clot Started on blood thinners, stopped birth control (had only been on birth control about 5-6 months)
COVID19 VACCINE	PFIZER\BIONTECH	1203844-1	50-59 years	6 days	4/1/2021: SEVERE LEG PAIN, PRESENTED TO HOSPITAL ER AND WAS FOUND TO HAVE ACUTE DEEP VENOUS THROMBOSIS LEFT LOWER EXTREMITY. 4/4/2021: SEVERE SHORTNESS OF BREATH, SQUEAD WAS CALLED AND HE WAS TAKEN TO HOSPITAL ER WHERE HE WAS FOUND TO HAVE BILATERAL PULMONARY EMBOLISM
COVID19 VACCINE	PFIZER\BIONTECH	1204261-1	65+ years	6 days	Pulmonary embolism
COVID19 VACCINE	PFIZER\BIONTECH	1211001-1	65+ years	6 days	Patient is deceased. Had a blood clot travel to her brain and causes an un recoverable stroke
COVID19 VACCINE	PFIZER\BIONTECH	1235719-1	30-39 years	6 days	left arm swelling started from 4/18, extended from upper arm to lower arm in the afternoon. went to Urgent care on 4/19 morning, the NP reviewed my blood report and referred me to do ultrasound and also ask me to go to ER if the swell extend. as the swell extend, i went to ER in the afternoon. blood test shows high D-dimer and then ultrasound finds blood clot in the vessel near left neck. diagnosed to be Deep Vein Thrombosis. no family history of such problem. in the hospital, they gave me a shot of blood thinner and also prescript oral blood thinner to be take at home.

COVID19 VACCINE	PFIZER\BIONTECH	1258763-1	50-59 years	6 days	On April 23,2021 patient was at her home and started complaining of shortness of breath and chest pain. She called 911 and they responded to her residence at 0500 a.m. While being assessed, patient collapsed. She was asystolic. CPR was started but to no avail. She was transported to the coroner's office where an autopsy was performed. She had bilateral pulmonary thromboemboli. There were not deep vein thromboses found in her legs.
COVID19 VACCINE	PFIZER\BIONTECH	1269555-1	65+ years	6 days	Pulmonary embolism; tested positive for Covid/shortness of breath/severe cough/headache; tested positive for Covid/shortness of breath/severe cough/headache; This is a spontaneous report from a contactable nurse (patient). The nurse reported similar events for herself and her daughter. This is the first of two cases. A 69-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine), the first dose administered in the right arm on 14Mar2021 (Batch/Lot Number: EN6208) and the second dose administered in the left arm on 03Apr2021 at 10:45 (Batch/Lot Number: ER8737), both intramuscular as a single dose for COVID-19 immunization. Medical history included diabetes and high blood pressure both diagnosed 5 years ago, GERD and hypercholesteremia, all ongoing. The patient was a former smoker but has been smoke-free for 15 years. Concomitant medications included rosuvastatin calcium (CRESTOR) taken for hypercholesterolaemia from an unspecified start date and ongoing; lisinopril (manufacturer unknown) taken for high blood pressure from an unspecified start date and ongoing; metformin (manufacturer unknown) taken for diabetes from an unspecified start date and ongoing and omeprazole (manufacturer unknown) taken for gastroesophageal reflux disease from an unspecified start date and ongoing. The patient did not have any prior vaccinations within 4 weeks of the COVID vaccine. The patient reported that she and her daughter had their second dose of the vaccine on 03Apr2021. The patient tested positive for Covid. The patient developed shortness of breath on Sunday, 11Apr2021, and ended up with a pulmonary embolism. The patient doesn't know if she was possibly infected before they got the second vaccine and were asymptomatic and unknown or did they get infected when got they got the vaccine with thousands of other people. At the time of the report, the patient was mostly resolved and they are all home. She became short of breath, had severe cough and headache and she went to the ER and on the CAT scan they discovered she had a small pulmonary emboli. She was hospitalized from 11Apr2021-12Apr2021. The patient was given Eliquis and monoclonal antibodies as treatment for the events. The patient stated that she will be on Eliquis for the next month because of the pulmonary embolism. The patient did not need any additional therapies for COVID-19. The patient did not have any pre-existing diseases that worsened during the SARS-CoV2 infection. The outcome of the event 'tested positive for Covid/shortness of breath/severe cough/headache' was not recovered while the outcome of the event pulmonary embolism was recovering. The relatedness of the suspect drug to the reactions was unknown.; Sender's Comments: Based on the information provided by the reporter, it appears reasonable that the suspect drug did not contribute to the development of the reported event pulmonary embolism, that most likely was related to the concurrent development of COVID-19. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021413236 same reporter and drug, similat event, different patient

COVID19 VACCINE	PFIZER\BIONTECH	1269617-1	65+ years	6 days	<p>Got worse and the leg swelled and was also having foot swelling because blood flow wasn't there; sore arm; blood clot; pain behind left knee; This is a spontaneous report from a contactable consumer (patient's wife). An 81-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration, administered in right shoulder on 23Feb2021 (Batch/Lot Number: EN6202) (at the age of 81-years-old) as single dose for covid-19 immunisation. Medical history included diabetes mellitus, stage 3 renal failure (was not bad, was in stage 5 couple of years ago, was a month or so away from full failure, was in the hospital and had dialysis, was able to get reversed with medication and diet), high blood pressure, and blood cholesterol increased/high cholesterol. The reporter stated that with regards to patient's height, he shrunk a little. Patient had no prior vaccinations within 4 weeks, didn't get flu shots. Concomitant medications include about 12 other unspecified drugs, takes statins, has high blood pressure and high cholesterol. Patient started experiencing pain behind his left knee about 6 or 7 days later in Mar2021 (also reported as 04 or 05Apr2021, pending clarification). By that Sunday, it had gotten worse. The leg swelled and was also having foot swelling because blood flow wasn't there. There was no TIA's no stroke, no heart racing, no sweating, was all pain. Got leg up and kept elevated until they could get to the doctor and get imaging. Patient went Monday 08Mar2021 to see the doctor. Patient was brought to the doctor and was then sent to the imaging place. Radiology read the imaging around 5:15pm on the Monday, 08Mar2021. The radiologist said there was 2.5" blood clot behind the left knee. He had never had a blood clot before. Patient was then sent to the Emergency Room at (Name) Hospital, in (Name) where they live. Was kept there several hours. Did a lot more blood tests. He was immediately put on 10mg ELIQUIS 10mg, once in the morning, and once at night. He is now taking 5mg Eliquis in the morning, and 5mg at night. He has not had any of these problems before the Pfizer shot. The reporter knew that not a lot had been reported. It seemed it should be safe. The correlation and timing having the shot on 23Feb2021 and all of a sudden a week and a half later this happened. It was 10 days later. There was nothing they can do about it. Just continuing with the ELIQUIS, trying to dissolve the blood clot, will be staying on it for 4 to 6 months. It was a pretty big blood clot and were worried about it breaking up and traveling. The patient had no other symptoms, had a sore arm, that was it. Patient going back to (Name) 01Jun2021 and he will have another CT scan or ultra sound when they get back. The reporter did not want to need to get the leg amputated. Patient was only in the ER, was not admitted to the hospital. Patient was concerned because of his age. If it doesn't dissolve, they know there will be a lot more trouble. The event of pain left knee, blood clot and sore arm required a visit to the emergency room and physician's office. The patient received the second dose of BNT162B2 on 01Apr2021 (lot number: ER8730) in the right arm. The outcome of events was unknown.""</p>
COVID19 VACCINE	PFIZER\BIONTECH	1277344-1	50-59 years	6 days	<p>headache; nausea; light headed/ dizziness; unsteady gait; vomiting; chills; sweats; superficial blood clot; pain to back of Rt knee; bruising; swelling; This is a spontaneous report from a contactable Nurse. A 57-year-old non-pregnant female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly, administered in Arm right on 31Mar2021 (Batch/Lot Number: EW0150) (at age of 57-year-old) as single dose for COVID-19 immunisation. Medical history included osteoarthritis, and migraines. The patient's concomitant medications were not reported. The patient previously took the first dose of BNT162B2, intramuscularly, administered in left Arm on 10Mar2021 (at age of 57-year-old) (Lot number: EN6207) for COVID-19 immunisation. It was unknown if other vaccine in four weeks. It was unknown if COVID prior vaccination. The patient experienced onset of pain to back of Rt knee, bruising, and swelling on 06Apr2021. She called doctor on 09Apr2021, provider diagnosed her with superficial blood clot. Treating with applying warm compress to area. Client had onset of headache, dizziness, nausea, light headed, unsteady gait, vomiting, chills and sweats on 10Apr2021. Patient called doctor on 14Apr2021, they recommended covid-19 testing, results are negative on 12Apr2021. Symptoms ongoing since 14Apr2021. The outcome of events was not resolved.; Sender's Comments: Based on plausible temporal association, a causal association between the reported event thrombosis and suspect drug bnt162b2 cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1288411-1	50-59 years	6 days	sustain cramps in her right leg; limited range of motion; not sure if there was a nerve that has been damaged or early stage of thrombosis; not sure if there was a nerve that has been damaged or early stage of thrombosis; severe arm pain; This is a spontaneous report from a contactable consumer reporting for herself. A 56-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number/expiration date: not provided), via an unspecified route of administration, on 12Apr2021 at 09:30 (at the age of 56 years old) as a single dose in the right arm for COVID-19 IMMUNIZATION. Relevant medical history and concomitant medication was none. The patient did not have any known allergies. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not pregnant at the time of vaccination. On 18Apr2021 at 18:00, the patient experienced severe arm pain that was described as arm pain was too painful and have been woken up out of her sleep and she has limited range of motion and she was not sure if there was a nerve that has been damaged or early stage of thrombosis. On 20Apr2021, the patient experienced sustain cramps in her right leg. The patient did not receive treatment for the events. The outcome of the events was not recovered. Since the vaccination, the patient had not been tested for COVID-19. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up.
COVID19 VACCINE	UNKNOWN MANUFACTURER	1219550-1	40-49 years	6 days	On 4/15 - patient presented with dull ache/pain behind right knee and sought medical treatment to address and diagnose possible issues.
COVID19 VACCINE	JANSSEN	1112822-1	65+ years	7 days	Pulmonary embolism one week after injection
COVID19 VACCINE	JANSSEN	1134819-1	50-59 years	7 days	She developed a large pulmonary embolus, and she died on 3/17 at Hospital. She developed symptoms of SOB on 3/11, and was admitted to the hospital. She was initially stable and not requiring oxygen and was sent home on anticoagulation. However she returned the same day with worsening symptoms, troponin now elevated, and ECHO showing signs of right heart strain. Embolus on imaging had increased in just over days from previous CT scan. She became pulseless and died despite resuscitative efforts. It is my opinion (Dr.) that she died of a pulmonary embolus, and an autopsy is pending.
COVID19 VACCINE	JANSSEN	1195446-1	60-64 years	7 days	Blood Clots in legs and lungs
COVID19 VACCINE	JANSSEN	1198162-1	40-49 years	7 days	My sister received the Janssen vaccine on March 13, 2021. One week later, March 20, 2021, she started complaining of severe headaches, dizziness and vomiting. This continued so she visited the ER on Wednesday, March 24, 2021, where she suffered a cerebral venous sinus thrombosis. She was pronounced brain dead on March 27, 2021, which is also the same day she was pronounced dead.
COVID19 VACCINE	JANSSEN	1200320-1	18-29 years	7 days	Flu-like symptoms. Muscle cramping in the left leg. Continuous period with heavy blood clotting.
COVID19 VACCINE	JANSSEN	1201835-1	50-59 years	7 days	Low grade fever, aches & chills on 3/13/21 & 3/14/21. Felt better 3/15/21 through 3/18/21. Side effects ( fever, aches, chills ) returned on 3/19/21 & 3/20/21. Suffered stroke on 3/21/21 at 3:30 AM due to blood clots. Passed away on 3/22/21.
COVID19 VACCINE	JANSSEN	1202804-1	40-49 years	7 days	My wife was sent to the ER with a headache this morning and has confirmed cerebral embolism
COVID19 VACCINE	JANSSEN	1204211-1	60-64 years	7 days	extreme shortness of breath after one week and admitted to hospital with blood clots in both lungs and a collapsed lobe in right lung within two weeks
COVID19 VACCINE	JANSSEN	1204622-1	30-39 years	7 days	Day of vaccine- Within hours, site soreness, raised red, approx size of a quarter, mildly painful, with a ""lump (that is still palpable) under the surface of the skin"". Within 5-6 hours following vaccine administration, she reports she developed fever, chills for approx 2 days with fatigue and hot flashes on and off. ** On 4/7/2021, patient states that in the morning she developed pain in her right calf. She saw her PCP.""
COVID19 VACCINE	JANSSEN	1206779-1	30-39 years	7 days	Pt received vaccination. Pt reports that she started feeling more fatigued and short of breath the week following injection. However, on 09Apr2021 pt had increased SOB and chest pain while shower, went into the doctor. After scan discovered Massive PE. Pt decompensated quickly and required intubation. Upon transfer to medical center, there were complications with ET tube and pt coded and required resuscitation for 6 minutes. Pt recovered and was transferred. Pt had Chest Xray, doppler of Bilateral lower extremities. Confirming PE and also left Popliteal DVT. Pt was on heparin drip which was switched to lovenox for proper anticoagulation. Pt was extubated on the 11th, is recovering. .
COVID19 VACCINE	JANSSEN	1207642-1	18-29 years	7 days	Extensive RLE and DVT, Xarelto initiated on 4/7/21 revealed the clinical finding. Patient in good condition.
COVID19 VACCINE	JANSSEN	1208879-1	60-64 years	7 days	Left saphenous superficial vein thrombosis

COVID19 VACCINE	JANSSEN	1209369-1	40-49 years	7 days	On April 2, 2021 the Janssen shot was provided with no adverse events. On April 9, 2021, a sever migraine developed along with a blue line in left leg.
COVID19 VACCINE	JANSSEN	1209679-1	60-64 years	7 days	Patient received his J&J vaccine for COVID-19 on 03/10/2021. On 3/17, he was at the grocery store when he felt a sting on his left lateral ankle. When he pulled up his pant leg, he saw the small little red spots that were exquisitely tender. He went immediately to his primary care physician's office, where he was prescribed Bactrim for suspected cellulitis. The rash steadily worsened with extension up his left leg and onto his right leg and blistering of some of the lesions most markedly in his groin. Pain associated with the rash increased and remained most severe on the lateral aspect of the left ankle. He presented back to his primary care physician's office on 3/19, where he was given methylprednisolone 80 milligrams IV, discharged with a prescription for prednisone 60 milligrams daily for the next few days. Pain worsened the morning of 3/20/21 to the point that he was unable to bear much weight on the left leg prompting his presentation to the emergency department.
COVID19 VACCINE	JANSSEN	1209984-1	50-59 years	7 days	DVT right common femoral vein, sent to hospital for Heparin, transitioned to Eliquis. Monitoring. Will follow-up with vascular specialist.
COVID19 VACCINE	JANSSEN	1210103-1	40-49 years	7 days	nausea, vomiting, diaphoresis, dizziness, headaches, bilateral tranverse sinus thrombosis
COVID19 VACCINE	JANSSEN	1210142-1	18-29 years	7 days	Patient was working and fell on the job due to what was perceived to be a seizure. Paramedics were called, and patient was taken to the emergency room. Initial reports from the hospital are that patient has clotting in the arm around the injection site. Patient is still at the hospital at the time of this report.
COVID19 VACCINE	JANSSEN	1212090-1	50-59 years	7 days	Systemic: Visual Changes/Disturbances-Severe, Additional Details: patients wife called to say that around 1 week after vaccine pt experienced vision issues. dr say he had a blood clot in eye which lead to partial blindness in one eye.
COVID19 VACCINE	JANSSEN	1212831-1	65+ years	7 days	STroke April 6 at hospital I am PCP, not admitting doctor I wanted to be sure you were aware of thromboembolic event
COVID19 VACCINE	JANSSEN	1215069-1	50-59 years	7 days	patient developed DVT and stroke on 4/8 however she had been in hospital from 3/31 to 4/5 with SMART syndrome and L sided weakness . after discharge she was inactive. returned to hospital on 4/8 with stroke in the region of SMART syndrome. Smart syndrome can cause stroke, but does not cause DVT. platelets are normal.
COVID19 VACCINE	JANSSEN	1217619-1	65+ years	7 days	Systemic: Blood Disorder (diagnosed by MD)-Severe, Systemic: blood clot in the lungs and legs-Severe, Additional Details: Per patient he went to the hospital on 3/17/21 and 3/23/21 and was diagnosed with a blood clot in his lungs as well as his legs. He was treated with Pradaxa but still continues to have difficulty walking and has overal body aches.
COVID19 VACCINE	JANSSEN	1217818-1	50-59 years	7 days	DVT Right Lower Extremity
COVID19 VACCINE	JANSSEN	1220382-1	65+ years	7 days	Acute bilateral lower extremity DVT found on venous duplex after reporting new bilateral leg swelling 7-8 days after receiving Janssen COVID-19 vaccine. No prior history of DVT. Brain MRA pending at time of report w/ concurrent history of new/moderate/persistent headache.
COVID19 VACCINE	JANSSEN	1221315-1	50-59 years	7 days	Patient started noticing left arm swelling and pain about 2-3 weeks after the vaccine. She then presented to the hospital 4/16/21 and was found to have a deep vein thrombosis in her left brachial vein as well as a thrombosis in her right internal jugular vein. She is currently being further worked up and will be admitted to the hospital for anticoagulation.
COVID19 VACCINE	JANSSEN	1222435-1	40-49 years	7 days	Left leg peroneal DVT
COVID19 VACCINE	JANSSEN	1223054-1	40-49 years	7 days	It started with pain on the left side and shortness of breath. She was taken to Medical Center and there diagnosed with splenic infarction due to blood clotting. Was prescribed pain medication and blood thinners (Lovenox) to be injected daily for three months.

COVID19 VACCINE	JANSEN	1226180-1	50-59 years	7 days	52-year-old previously healthy female who received first dose of Janssen COVID-19 vaccine on 4/7/2021. She started having periorbital right headaches starting on or about 4/14/2021. Headaches were alleviated with OTC Advil. On the morning of 4/18/2021, she awoke with RIGHT arm weakness which, over the course of several hours, progressed to include right-sided leg weakness and aphasia. Initial CT head showing multifocal hemorrhage within the LEFT frontal lobe. Course complicated by epileptic seizure. MRI brain with and without contrast and CT venogram brain notable for superior sagittal sinus thrombosis involving the mid and anterior segments of the superior sagittal sinus. Patient found to have new thrombocytopenia on admission with platelet level 78k; previously had normal platelets 6/4/2019. D-dimer elevated > 4.00 mcg/ml FEU. Started on Argatroban gtt, nicardipine, and IVIG.
COVID19 VACCINE	JANSEN	1228968-1	18-29 years	7 days	Started with chest pain, a couple of days after the shot. Fainted on 3/13/21, transported by EMS to emergency room. CT scan was done, Dr. said she has blood clots in her lungs. Was given a prescription for Eliquis 5 mg twice daily.
COVID19 VACCINE	JANSEN	1230513-1	50-59 years	7 days	Approximately a week after vaccine, I began to have Claudication pain in right leg that progressed to critical limb ischemia with 4 weeks requiring surgery to remove serial clots in right lower extremity.
COVID19 VACCINE	JANSEN	1231017-1	60-64 years	7 days	ultrasound found first blood clot behind left knee on 3/18/21....Another clot on left ankle on 4/08/21.... Another clot on left shin on 4/16/21.... Doctor prescribed Xarelto on 3/18/21... Since that date the 2 later blood clots have formed... I have NEVER had a blood clot before receiving Jansen vaccine at a community church on 3/11/21
COVID19 VACCINE	JANSEN	1237959-1	60-64 years	7 days	Superficial vein thrombosis in left thigh that was reported to a primary care provider on 3/19, 6 days after the vaccine was given.
COVID19 VACCINE	JANSEN	1238255-1	65+ years	7 days	patient came in for routine physical exam on 4/12. had gotten J/J vaccine on 3/17. husband reported onset of dyspnea a few weeks prior, eg starting some time after her vaccine. worsened significantly 2-3 days prior to her physical, but she refused to go to hospital. was found to be hypoxic at her routine physical and sent by ambulance to ED, had large saddle PE requiring thrombolysis, left leg DVT. was in ICU. now home off oxygen on anticoagulation.
COVID19 VACCINE	JANSEN	1239214-1	65+ years	7 days	Left upper extremity DVT in brachial vein. Left upper extremity SVT in basilic vein. Started on xarelto, plan for 3 month course. Sepsis - no source
COVID19 VACCINE	JANSEN	1239307-1	40-49 years	7 days	Blood clots in urine on 04/16/21. Severe blood clotting in urine on 04/17/21. Symptoms improved on 04/18/21.
COVID19 VACCINE	JANSEN	1242429-1	60-64 years	7 days	developed swelling and pain left arm within 1 week of administration Janssen Covid -19 vaccine IM left arm on 3/27/2021, on 4/16/21 left upper extremity venous sonogram demonstrated left axillary vein thrombosis
COVID19 VACCINE	JANSEN	1248051-1	65+ years	7 days	Patient was admitted with ischemic colitis and hypoglycemia. She also tested positive for C.diff during her hospitalization, unclear if this was from prior antibiotics in March. She did not receive DVT prophylaxis for 2 days. She developed a nonocclusive DVT in the right internal jugular and subclavian veins and a Nonocclusive superficial thrombosis in the right basilic vein on 4/18. She went into PEA and was revived, intubated, and transferred to the ICU. She went into PEA again and was revived after 5 rounds of CPR. The family decided to make the patient comfort care and expired on 4/19
COVID19 VACCINE	JANSEN	1259704-1	40-49 years	7 days	Went to er on April 11 th for cough and shortness of breathe they said nothing was wrong and sent me home. Did a virtual apt on 21st because my leg hurt and shortness of breathe. They told me to go see doctor in person . Went to Er April 23rd and was diagnosed with a massive blood clot in my lower right leg.they prescribed xarelto.
COVID19 VACCINE	JANSEN	1263262-1	50-59 years	7 days	Patient received J&J vaccine at 4/6/21. She began complaining of calf pain 1 week later. She was diagnosed with DVT and started on Eliquis 10 mg PO BID x 7 days on 4/15/21, followed by 5 mg PO BID on 4/22/21. She continued to complain of shortness of breath. CT chest was done to rule out PE. She was diagnosed with PE and sent to the emergency room for a continuous heparin drip (despite adequate anticoagulation with Eliquis) She is saturating at 97% on room air. Her BP is stable. She is afebrile Of note, she is morbidly obese Her height is 64 in (5' 4''') Her weight is 106 kg (233 lbs) Her BMI is 39.99 kg/m2 She is not on any hormone replacement therapy, contraceptives, etc. Her last known use of oral contraceptives was 10 years ago. She is not an active smoker''''

COVID19 VACCINE	JANSEN	1264226-1	65+ years	7 days	patient reported to hospital with headache for 2 days, and was told she had a blood clot in her liver last week. she reports that she got the Johnson and Johnson vaccine last month. exact date not known.
COVID19 VACCINE	JANSEN	1270278-1	40-49 years	7 days	Next day full body red rash, 103-104 degree fever, deep body aches, skin sensitivity, joint pain, headache, brain fog, lasted 4 days, One week later period started with large chicken-egg sized blood clots, heavy flow lasted 2 days longer than typical period for me. Second cycle after vaccine started 4.22.21 with same very large clots, intense cramping and bloating
COVID19 VACCINE	JANSEN	1271104-1	50-59 years	7 days	Immediately after the injection patient felt a pressure like and felt a ball on the back of his head left side that resolved within a day. Within a week from vaccine patient started having a headache on and off with feeling of like his brain is swelling on the left side. Within another week patient experienced abdominal pain and chest pressure. went to a hospital CT abdomen was negative. On 4/28 patient had a severe headache followed by numbness to left face and left facial droop. 911 was called patient was code stroke in ED.
COVID19 VACCINE	JANSEN	1275007-1	50-59 years	7 days	patient was fine until a week later when started getting dizzy and throwing up. taken to ER, but didn't tell them had been vaccinated. Couldn't find anything wrong and was sent home after a few days. Went to ER again and this time wife told them he had been vaccinated week before symptoms started. Did brain MRI and found a blood clot. Pt currently in rehab.
COVID19 VACCINE	MODERNA	0955565-1	18-29 years	7 days	One week after the shot (1-14-2021) Patient (19 y.o.) reported side pain and appeared constipated, Laxatives given along with Tylenol, on further assessment Patient was noted to have left leg redness and abdominal fullness. Dr. was updated and we had orders for close monitoring, the next day when she got up, her leg appeared better, and she had passed a small BM, but by lunch she had developed significant pain and edema in her left leg, and the color of her leg was reddened again. She was sent to the emergency room with her symptoms. She was admitted back to our facility yesterday, her diagnoses included Acute provoked left external iliac, femoral, popliteal, and peroneal DVT. Elevated Factor II levels, Elevated APC resistant, May-Thurner Syndrome, history of developmental disabilities, fecal impaction and urinary retention - suspected related to her fecal impaction. Vascular surgery was consulted, and pt. was started on a heparin drip, and mechanical thrombectomy was needed for both legs due to multiple clots. She was started on Eliquis and Plavix, and thigh high compression stockings were ordered, ace wraps being used until these are supplied. Her Fecal impaction was addressed also and the urinary retention resolved.
COVID19 VACCINE	MODERNA	0971609-1	65+ years	7 days	71 yo M admitted for sepsis from perforated gangrenous cholecystitis c/b E coli bacteremia, s/p lap chole 1/14 then found to have post-op collections now s/p drain placement of medial collection and aspiration of lateral collection. CT evaluation for pulmonary emboli on 1/22/21 discovered, ""Bilateral upper lobe segmental/subsegmental pulmonary emboli. No evidence of pulmonary infarct or right heart strain.""
COVID19 VACCINE	MODERNA	1017556-1	65+ years	7 days	Patient has been weak and having difficulty urinating for the few days. Was unable to urinate this morning and made an appointment. On the drive to the appointment, he felt the urge to urinate and urinated in a urinal he had with him. The urine looked like blood with clots. Patient admits that he has had some clots in his urine for past week, so he had taken plavix to break up the clots (plavix is not his medication). Given weakness, difficulty urinating, and gross hematuria, patient was sent to the ER. ER nurse was called and given report

COVID19 VACCINE	MODERNA	1040934-1	65+ years	7 days	-Approximately 5 hours after injection, developed 12 hours of chills (no fever), diffuse aching, fatigue, and very low energy. -Approximately 3 days after vaccine noted difficulty completing usual daily exercise routine- stamina appeared low. -Approximately 3-5 days after vaccine noted difficulty completely taking in deep breath, with ""catch"" or discomfort in substernal area. -During early morning hours of day 7 after vaccine, was awakened with sharp, intense toothache pain right flank. With change of position was able to get comfortable after which pain resolved. This reoccurred the next two nights prompting ED visit. -First ED visit focused on right flank pain and CT Abdomen and pelvis was negative except for ""atelectasis"" right lung base -Due to more pleuritic symptoms, second ED visit occurred, and CT chest with contrast demonstrated bilateral PEs (approximately 5 on right and 2 on left) with evidence for RV strain -Hospitalized and started on anticoagulation (Lovenox SQ for one dose and then Eloquis). Echocariogram confirmed mild RV dilatation. Interventional Radiology did not feel removal/lysis of clots necessary. -Completed exhaustive evaluation with Hematology--no underlying clotting disorder identified to date -Have returned to 100% activity without significant symptoms at present""
COVID19 VACCINE	MODERNA	1059137-1	65+ years	7 days	The patient had bilateral Pulmonary Embolisms on February 8th. recommended we report this and any major incident a patient might have within 1 month of administering the vaccination.
COVID19 VACCINE	MODERNA	1065976-1	65+ years	7 days	Pulmonary Embolus, hospitalized. Released by hospital 2 days after event. Blood Thinners and pain medication.
COVID19 VACCINE	MODERNA	1075784-1	65+ years	7 days	About a week after receiving my second Moderna Covid shot I felt shortness of breath. 9 days after the shot I had a mild fever (100.5f), severe shortness of breath and chest pain (level 5+) and went to the emergency room. They found D/Dima was elevated and sent me for a CT scan. This showed a significant blood clot in the right lung and a lesser dot in the left. I am usually extremely health, walking 2 miles at least 5 days a week and bicycling about 50 miles per week
COVID19 VACCINE	MODERNA	1089580-1	65+ years	7 days	Injection to shoulder went in vein rather than muscle; bleeding. A week later left ankle swelling, turned worse, calf starting cramping and swelling. On next Monday went to Hospital for ultrasound. Diagnosis: 2-foot long blood clot, DVT. CT Venogram taken February 11 no cause found. Went to hematologist did full blood panels. No cause found. Diagnosis: only alternative cause: COVID-19 vaccine.
COVID19 VACCINE	MODERNA	1092762-1	40-49 years	7 days	I experienced a runny nose with mucus, blood running from nose with blood clots four to five times a day from March 8th 2021 up to March 10th 2021. It is unknown rather I have blood clots within my body.
COVID19 VACCINE	MODERNA	1093498-1	65+ years	7 days	Site: Swelling at Injection Site-Severe, Systemic: DVT-Severe, Additional Details: Patient presented to office with swelling of right upper extremity occurring after first COVID 19 vaccine dose. Was sent for duplex study which revealed acute deep vein thrombosis in right subclavian and axillary veins and superficial thrombophlebitis of basilic vein in right arm. Pharmacy was contacted 3/10/2021 by MD at hospital to report vaccine adverse event
COVID19 VACCINE	MODERNA	1097343-1	65+ years	7 days	Pulmonary Embolism in right lung, lower lobe. Heparin for two days in hospital and Eliquis starter pack once I was discharged
COVID19 VACCINE	MODERNA	1104841-1	65+ years	7 days	My husband received the first injection on Feb 3, 2021 he developed a cough afterwards, cough would come and go. He was scheduled to receive 2nd dose on March 11 and I was concerned about having a cough at the time of 2nd vaccine. He went to walk-in clinic and got a covid test was negative, he said his exam was normal, they gave him prescription of Benzonatate 100mg he took one and it did not help so he never took any more. On March 5 while working in the yard he collapsed, paramedics arrived and he was in cardiac arrest, they started CPR, they used AED was in vfib, he was taken to Hospital then transferred to second hospital. I was told he had blood clots in both lungs, one in his leg, and possible clots in the mesenteric area of abdomen. His heart stopped due to the blood clots in his lungs. He remains in the hospital in the Intermediate Coronary Care Unit. He has not yet gained full consciousness.

COVID19 VACCINE	MODERNA	1106802-1	65+ years	7 days	One week after 2nd Moderna, started coughing periodically in day and night chest congestion started to build at night. After three days of cough periodic and each night became more congested with problem being to not inhale deeply, and lower right side adobonem pain. Sought medical appointment March 20 but did not get appointment until March 9 with medical facility due to increasing pain and not sleeping from congestion. March 10 doctor visit ordered blood and urine tests and CT scan. Early Mar11 test B type natriuretic protein was high (CHF), Doctor ordered chest xray, ekg and echogram. CT scan found clot in right lower lung. Told to go to ER Mar 10 evening, ER ordered Ultrasound images of the legs.BILATERAL LOWER EXTRE BILATERAL LOWER EXTREMITY DEEP VEINS: Nonocclusive thrombus in the distal right femoral vein and popliteal vein extending into the tibioperoneal trunk. Thrombus is hypoechoic and expansile consistent with acute thrombus.Left lower extremity veins are patent and compressible. Left common femoral vein demonstrates normal waveform without loss of respiratory phasicity.Positive for right lower extremity DVT of the distal femoral vein, popliteal vein, and tibioperoneal trunk. CT;LUNG BASES: Small right pleural effusion with overlying compressive atelectasis and consolidation. There are addition, there are apparent filling defects within the subsegmental pulmonary arterial branches suggestive of emboli. Many /multiple blood tests March 9, 10 ,11 , 12 and 16 available to examine details..one perhaps low Platelets count 151 K/uL (range) 140 - 400 K/uL. I can give permission for these tests results to study to correlate lung and leg clots . This is unique because hospital data available to diagnose in detail my reaction after 2nd Moderna shot. Please look into it with experts..Did Moderna cause my clots I never had before?
COVID19 VACCINE	MODERNA	1122080-1	40-49 years	7 days	Patient's received 2nd dose of Moderna vaccine Friday 3/12. Her husband reported she had not unexpected fatigue, malaise, and fever for 1 day but better after that. On Monday she began complaining of shortness of breath. This progressively worsened and she started having presyncopal episodes. On Saturday she was unable to come down the stairs in the house so husband planned to take her to the hospital but she stood up and passed out and woke up quickly. He decided to call EMS. By the time she presented to our hospital she was cyanotic and agonal breathing. On moving her from EMS stretcher to ED bed she had PEA cardiac arrest. She underwent mechanical device CPR with only brief (<1 min) ROSC x1. She at some point did have a shockable rhythm. Cath lab was notified and she was taken emergently to the cath lab with ongoing mechanical device CPR. Peripheral VA ECMO was placed after about 1.5 hours. Pulmonary angiogram was done which showed massive saddle PE with near complete obliteration of the right pulmonary tree and some filling defects in the left tree as well. At that time she had severe mixed respiratory and metabolic acidosis with a lactate of 24. She also had no gag or corneal reflex, minimally responsive pupils, and no response to noxious stimuli. Mechanical thrombectomy was attempted with some result. She was transferred to the SICU with increasing pressor requirement, and DIC. Ultimately, the venous catheter of the ECMO circuit malfunctioned thought to be secondary propagating IVC thrombosis. Family decided to withdraw care and she passed away.
COVID19 VACCINE	MODERNA	1154606-1	65+ years	7 days	Patient began having symptoms 7 days after vaccination: chest pain, shortness of breath, feeling like a lump in the throat. Over several days symptoms worsened, and included upper back pain and some pain in the upper left arm. Patient went to urgent care clinic on the morning of March 15, where staff decided to send patient by ambulance to the hospital. She was admitted to the hospital and diagnosed with having 5 blood clots in her lungs. She was discharged March 16 in the evening on Eliquis 5mg twice a day. She states the hospital did not know what caused the blood clots, and were aware she had been vaccinated recently. She has not had a doctor visit in years, but is now established with a primary care physician for follow-up care. The second Moderna dose was given today 3/31/21.
COVID19 VACCINE	MODERNA	1163787-1	65+ years	7 days	Patient presented to our ED on 3/30/21 @ 1149 with complaints of SOB and chest pain. D-Dimer was elevated > 3 times upper normal limit so CTA was performed. CTA showed bilateral lower lobe PE with moderate thrombus burden. Patient was given Lovenox 1mg/kg (90 mg) x 1, pain medication, and home medications he had not yet taken at home on 3/30. He was then transferred to a higher level of care. Course at transfer hospital unknown at this time.
COVID19 VACCINE	MODERNA	1184428-1	65+ years	7 days	Diagnosed with multiple pulmonary emboli after presenting to ED with pleuritic chest pain and DOE. Unclear time of onset of symptoms, possibly preceding 2nd dose of vaccine by about 1 month. unclear temporal relation to initial vaccine dose.

COVID19 VACCINE	MODERNA	1188857-1	50-59 years	7 days	experienced blood clot; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (experienced blood clot) in a 55-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 038A21A) for COVID-19 vaccination. Concurrent medical conditions included Factor V Leiden mutation. Concomitant products included RIVAROXABAN (XARELTO) for Factor V Leiden mutation. On 16-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Mar-2021, the patient experienced THROMBOSIS (experienced blood clot) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (experienced blood clot) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. The patient was treated with blood thinner Xarelto (rivaroxaban) on a daily basis for factor V mutation and was treated with the same for blood clot.; Sender's Comments: Limited information regarding the event has been provided at this time and a causal relationship cannot be excluded
COVID19 VACCINE	MODERNA	1192802-1	60-64 years	7 days	Blood Clots, Stroke
COVID19 VACCINE	MODERNA	1198613-1	65+ years	7 days	Eight days following the first vaccine I was admitted with massive blood clots to my lets and lungs. I was hospitalized for 8 days. Four days were in ICU.
COVID19 VACCINE	MODERNA	1201478-1	18-29 years	7 days	I was having intense chest pain, weakness/faintness feeling a few days after second dose of Moderna vaccine. I went into the ER after 4th day of pain. ER did a CT scan and found a couple blood clots in my right lung (pulmonary embolisms) along with tissue on lung. An ultrasound of my heart and legs were done to find the source of these blood clots and neither tests found blood clots or indicators that this is where they originated. I am currently in blood thinners in order to reduce the clots.
COVID19 VACCINE	MODERNA	1201641-1	60-64 years	7 days	Within 7 days of vaccine, I began experiencing aching of right posterior leg just below knee. Applied heat, elevated and just continued to ache intermittently, daily. Waited and disregarded as anything to worry about. After 2 wks of continued symptoms despite no redness, swelling or positive homans sign, being a health care professional (RN), I decided to seek evaluation at local ER to rule out DVT. On April 1st, I presented to ER, Address and number provided.completed and diagnosed with posterior tibial venous thrombosis on
COVID19 VACCINE	MODERNA	1202135-1	65+ years	7 days	Reporting for a friend she is in the hospital, all events may not be filled in, but I thought it was important to report sooner than later due to the news on other vaccines. Patient had her second shot around 3/7/2021 u sure as she is in a rehab facility time of day was 1630. On the 17 th of March she started having back pain then wasn't able to get herself to the hospital called 911 and was transported to the hospital and that night had emergency surgery for a blood clot in her neck. She was in rehab and got rushed back to the hospital and had a pacemaker placed. She is still in a rehab facility.
COVID19 VACCINE	MODERNA	1202613-1	65+ years	7 days	Seven days after Moderna vaccine I got up and started feeling a warmth in my leg that started in foot and went up and it started hurting really bad, called an ambulance and went to hospital and because of blood clots, I had to have emergency surgery, it was very huge arterial clot, and developed shingles as well.
COVID19 VACCINE	MODERNA	1205982-1	65+ years	7 days	On 1-27-21 my mother received her first dose of the Moderna COVID-19 vaccine (031L2A). The next day she felt something in the back of her left knee. The following day (2 days) after the injection she saw her primary care physician for the discomfort in the back of her knee. She was treated for what was believed to be a soft tissue injury. She received her second dose of the Moderna COVID-19 (14M20A) vaccine on Friday 2-26-21. The next day the back of her knee started to bother her again. She saw her doctor on Monday 3-1-21 and had an x-ray. On Tuesday the doctor's office called and said her x-ray was clear. Friday morning, 3-5-21 my father heard a loud noise (thud) and found my mother unresponsive on the bathroom floor at approximately 8:30am. He called 911. She was transported to the hospital via ambulance. The emergency room physicians worked on her for over an hour and were unable to get her back. Her time of death was 10:12am. The primary cause of death listed on her death certificate is pulmonary embolism.
COVID19 VACCINE	MODERNA	1206090-1	65+ years	7 days	Lost my vision and felt very weak. Doctor concluded I had a mild stroke(TIA), also they found a DVT in my right leg and DVT in my left leg. My vision returned in about 1 hour. Was given 2 shots a day of Lovonox for 13 days and was immediately put on Warfarin
COVID19 VACCINE	MODERNA	1209084-1	50-59 years	7 days	on 3/5/2021 pt had massive unprovoked pulmonary embolism with right heart strain requiring thrombectomy

COVID19 VACCINE	MODERNA	1214203-1	30-39 years	7 days	1 week of left sided chest pain/tightness, pleuritic in nature, some dyspnea with exertion, symptoms started 3/31, diagnosed with bilateral pulmonary emboli
COVID19 VACCINE	MODERNA	1235676-1	50-59 years	7 days	Blood Clotting; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood Clotting) in a 59-year-old female patient who received mRNA-1273 for COVID-19 vaccination. The patient's past medical history included No adverse event. On 26-Feb-2021, the patient received first dose of mRNA-1273 (Intramuscular) 1 dosage form. On 05-Mar-2021, the patient experienced THROMBOSIS (Blood Clotting) (seriousness criteria medically significant). At the time of the report, THROMBOSIS (Blood Clotting) had resolved. Not Provided. The action taken with mRNA-1273 (Intramuscular) was unknown. Treatment information was not provided. Concomitant medications were not reported. Company Comment: Very limited information regarding the events has been provided at this time and is insufficient for causality assessment. Further information has been requested.; Sender's Comments: Very limited information regarding the events has been provided at this time and is insufficient for causality assessment. Further information has been requested.
COVID19 VACCINE	MODERNA	1276697-1	65+ years	7 days	clot in her lungs; This spontaneous case was reported by a non-health professional and describes the occurrence of PULMONARY EMBOLISM (clot in her lungs) in a 76-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included No adverse event (No medical history reported). On 22-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 29-Jan-2021, the patient experienced PULMONARY EMBOLISM (clot in her lungs) (seriousness criterion medically significant). At the time of the report, PULMONARY EMBOLISM (clot in her lungs) had not resolved. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No relevant concomitant medications were provided. No treatment information was provided. Based on the current available information and temporal association between the use of the product and the onset date of the reported event of pulmonary embolism, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-075030 (E2B Linked Report); Sender's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the reported event of pulmonary embolism, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-075030:Patient's brother in law case; cross linked case
COVID19 VACCINE	MODERNA	1281531-1	30-39 years	7 days	Received 2nd dose of vaccine, 5 days later his left leg started hurting and swelling. He had severe headache afterwards, dizzy and blurred vision. 04/24/2021 he complained of not feeling right, coughed and passed out. Had fever and chills when he came to. Wife called 911 and was talking and walking. Was awake and talking in ambulance, oxygen level was low. Once arrived at hospital, he became restless and passed away within 3 minutes. Autopsy was performed due to his age - 35 and no pre-existing illnesses - was determined he died of Pulmonary Thrombo Embolism
COVID19 VACCINE	PFIZER\BIONTECH	0925640-1	60-64 years	7 days	DVT left calf; This is a spontaneous report from a contactable Physician (patient). A 60-year-old male patient started to receive the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Intramuscular on 20Dec2020 08:00 at single dose on right arm for COVID-19 immunization. Medical history included Gastric reflux. The patient had no known allergies. The patient had no covid prior vaccination. The patient had no covid tested post vaccination. Concomitant medications included omeprazole (PRILOSEC) and ergocalciferol (VIT D). The patient had not received other vaccine in four weeks. The patient experienced deep vein thrombosis (DVT) left calf on 27Dec2020 09:00 which resulted emergency room visit. Treatment received for the event included Xarelto. The outcome of the event was not resolved. Information on the lot/batch number has been requested.; Sender's Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

COVID19 VACCINE	PFIZER\BIONTECH	0943868-1	65+ years	7 days	Developed pulmonary embolism in right lung one week after vaccination. Sharp pain on right side when breathing. Treated with IV Apixaban while inpatient for 2 days, oral Apixaban 5 mg, 2 tabs twice daily 1/5/21-1/11/21, then one 5 mg tab twice a day. Pain has subsided as of 1/14/21.
COVID19 VACCINE	PFIZER\BIONTECH	0952872-1	65+ years	7 days	80YO male who htn, cva, epilepsy, kkd, cerebral avm s/p repair, cad s/p cab, cva (left sided hemiplegia) , hx of prostate cancer recent admission for pna on abx presents to ED on 1/11 with dizziness, hypoxia. CT with Bilateral PE ""Large bilateral pulmonary artery emboli in the right and left main pulmonary artery extending into the right and left main pulmonary artery branches bilaterally. Findings are associated with right-sided heart strain."" ""Patchy alveolar airspace disease within the lungs highly suspicious for COVID pneumonia"" Covid negative. Patients wife recovered from Covid-19 infection within last month. Patient thus far has tested negative. Doppler lower extremity revealed Acute occlusive vein thrombosis of the entire course of the gastrocnemius vein and soleal vein. Patient received covid vaccine on 1/4/21. Patient has several risk factors for clot - age, previous CVA, hx of prostate cancer. Also had positive covid exposure though tested negative""
COVID19 VACCINE	PFIZER\BIONTECH	0992061-1	40-49 years	7 days	Patient began having increasing shortness of breath about a week after receiving first dose of Pfizer COVID-19 vaccine. Symptoms worsened and persisted to the point where patient called her PCP on 1/26/2021, who advised her to report to ED if experiencing worsening symptoms and/or low oxygenation. Patient reported to ED on 1/29/2021 due to tachycardia and O2 sats <90%. On presentation, patient was found to have bilateral pulmonary emboli involving the upper and lower lobe regions bilaterally including segmental branches without evidence of right heart strain.
COVID19 VACCINE	PFIZER\BIONTECH	1000885-1	65+ years	7 days	1-7-21 - Posterior lumbar interbody fusion @ L3-4 (N/A spine lumbar) by Dr. 1-19-21 - 1st dose Pfizer Covid-19 vaccine given. 1-26-21 - Swelling of (R) calf (H/O peripheral edema) 1-29-21 - 1-31-21 - Hospitalized with DVT (R.leg) & PE (lungs bilaterally)
COVID19 VACCINE	PFIZER\BIONTECH	1012703-1	65+ years	7 days	1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.
COVID19 VACCINE	PFIZER\BIONTECH	1017411-1	65+ years	7 days	patient developed blood clot in her left groin one week after getting first COVID19 vaccine.
COVID19 VACCINE	PFIZER\BIONTECH	1040874-1	65+ years	7 days	Within one week of receiving vaccine, experienced shortness of breath and chest tightness on exertion, lightheadedness, tachycardia. Became increasing worse over next 5 days. Visit to ER on 1/18/21. Diagnosed with many bilateral pulmonary emboli with clots in both pulmonary arteries. Admitted to hospital and started on Eliquis. Had doppler on legs which showed DVT.
COVID19 VACCINE	PFIZER\BIONTECH	1041621-1	30-39 years	7 days	Vague onset of malaise, fever, exertional dyspnea, chest pain that progressed approximately 1-2 weeks after the 2nd dose of the Pfizer vaccine. Led to development of pericardial effusion with cardiac tamponade physiology, atrial flutter, and subsegmental pulmonary embolism. Workup of other causes of pericardial effusion (e.g., infection, malignancy, autoimmune), and hypercoagulability were otherwise negative. 2nd dose of vaccine was on 1/4/2021 and pericardial effusion was diagnosed and evacuated on 2/14/2021. Patient hospitalized from 2/14/2021-2/17/2021. Patient is also healthcare provider.
COVID19 VACCINE	PFIZER\BIONTECH	1063464-1	50-59 years	7 days	Patient had the first dose of the Pfizer COVID vaccine (LOT# EL9264) on 1/29/21 at the vaccination center at Medical Center (set up in Hotel). He had the second dose on 2/19/21 (LOT# EN6201) at 12:30pm, and reported leg pain and difficulty breathing on 2/26/21 as he was going to bed. He presented to the ER at Hospital that day, and was diagnosed with a deep venous thrombosis and pulmonary embolism. He is currently taking Xarelto, and will schedule an appointment with Hematology, as he has no family or personal history of clotting disorder.

COVID19 VACCINE	PFIZER\BIONTECH	1065118-1	50-59 years	7 days	Blood clot in lower left leg; This is a spontaneous report from a contactable consumer (patient herself). A 58-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), via an unspecified route of administration on the left arm, at age 58 years, first dose on 23Jan2021 14:00 at single dose for COVID-19 vaccination. Medical history was reported as none. Patient had no known allergies. The patient is not pregnant. There were no concomitant medications. There were no other vaccines administered in four weeks and no other medications taken in two weeks. On 30Jan2021, patient experienced blood clot in lower left leg. ER doc indicated that patient had no reason to have formed a clot given the medical history, health, weight, age, diet, no surgeries, no prior injury, etc. Facility type vaccine was administered at a Public Health Clinic/Veterans Administration facility. Event resulted in emergency room/department or urgent care. Therapeutic measures were taken as a result of the event includes rivaroxaban (XARELTO) as blood thinner. The outcome of the event was not recovered. Information about lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1107421-1	65+ years	7 days	I had sudden malaise, lost consciousness and my wife says was not breathing briefly. I revived and was taken to the hospital, and treated for 2 1/2 days with heart catheterization and TPA injected into my clot in the pulmonary arteries with good resolution. I did have cor pulmonale with acute severe right heart failure as part of that, Dr. thought the clot came from my right calf by his examination. Diagnosis was confirmed by CAT scan cardiac Echo and right heart catheterization.
COVID19 VACCINE	PFIZER\BIONTECH	1111727-1	65+ years	7 days	Developed extensive deep vein thrombosis and pulmonary embolism
COVID19 VACCINE	PFIZER\BIONTECH	1115965-1	60-64 years	7 days	Pt developed a new onset, acute deep vein thrombosis approximately 6-7 days after vaccination in the R lower extremity with extreme pain and inability to bear weight.
COVID19 VACCINE	PFIZER\BIONTECH	1116221-1	40-49 years	7 days	Woke up with pain in left leg lower calf on February 26 one week after my second vaccine. Had pain and throbbing in leg couldn't sleep with pain so on the evening of March 3rd I went to urgent care . Doctor didn't think it was blood clot because I had no swelling or redness in my leg but gave me a script for ultrasound. I couldn't get an appointment until the morning of March 5th . Was diagnosed with a very large blood clot in lower leg going up past my knee. I am now in Eliquis blood thinner for 3 months while they run tests
COVID19 VACCINE	PFIZER\BIONTECH	1139480-1	65+ years	7 days	high fever, headaches very ill. Neck stiff and the gland were swollen. could not eat or drink and severe pain and weakness.
COVID19 VACCINE	PFIZER\BIONTECH	1142935-1	65+ years	7 days	1 week after second dose I developed a blood clot behind my left knee, in hospital for 9 days; This is a spontaneous report from a contactable consumer (patient). An 87-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 17Feb2021 09:00 (Lot Number: EN6201) as SINGLE DOSE for COVID-19 immunization. Medical history included high blood pressure, controlled from an unknown date and unknown if ongoing and penicillin allergy from an unknown date and unknown if ongoing. The patient previously had first dose of BNT162B2 in the left arm (lot number: EL3244) on 20Jan2021 for COVID-19 immunization. Concomitant medications included apixaban (ELIQUIS), metformin, caredevil and fish oil; all taken for an unspecified indication, start and stop date were not reported. On 24Feb2021 12:00 PM, it was reported that the patient 1 week after second dose, developed a blood clot behind left knee, in hospital for 9 days that also resulted in emergency room/department or urgent care. The event was treated with blood thinners. The patient had no COVID prior to vaccination and has not tested for COVID post vaccination. The outcome of the event was recovering.
COVID19 VACCINE	PFIZER\BIONTECH	1154151-1	65+ years	7 days	FALLS, CHEST PAIN, HEMORRHAGIC CONTUSION, COVID, PNEUMONIA, HYPOXIC RESPIRATORY FAILURE Narrative: 2/22/2021 Patient presented to hospital with multiple complaints. He was reporting falls, chest pain, his wife was diagnosed with Covid. While he was there, he was found to have hemorrhagic contusion in the right frontoparietal region with minimal surrounding edema, Covid, pneumonia, elevated troponin. He was accepted in transfer by trauma surgeon Dr. and arrives with no complaints. 2/26/2021 Patient died after code blue was called Death Diagnosis: s/p fall with head trauma Focal area right intracranial hemorrhage per initial CT - serial CT head showing stability Acute hypoxic respiratory failure secondary to COVID-19 viral illness COVID-19 viral illness Acute chest pain, improved Elevated troponin, suspected type 2 NSTEMI Elevated D-dimer - V/Q scan with intermittent probability PE Acute kidney injury on CKD, improving unlikely that vaccine contributed to patient's death.

COVID19 VACCINE	PFIZER\BIONTECH	1154742-1	50-59 years	7 days	Thrombus of right middle cerebral artery at bifurcation of M1 and M2 causing stroke
COVID19 VACCINE	PFIZER\BIONTECH	1168453-1	60-64 years	7 days	Died 4 days after shot from blood clots in my lungs. No history of clotting before this. Did have Covid asymptomatic back in January. So not sure whether having had Covid caused the clotting. Having the vaccine or being out of work with torn meniscus. They think clots started in my legs and ended up in my lungs. I was brought back after coding for 6 minutes. They seem to think Covid caused it. Not sure if vaccine contributed or not. But it did happen 4 days after the shot.
COVID19 VACCINE	PFIZER\BIONTECH	1182724-1	65+ years	7 days	On Apr 7th at 11:30 Pm my wife went to hospital. not being able to breathe sufficiently. This started the day before on the 6th while out walking. She is in the hospital being treated for embolisms of the lungs on both sides with multiple blood clots.
COVID19 VACCINE	PFIZER\BIONTECH	1192317-1	50-59 years	7 days	pain in left leg calf, left side of chest DVT and PE 2 visits to Urgent Care Lovenox and Pradaxa
COVID19 VACCINE	PFIZER\BIONTECH	1205071-1	65+ years	7 days	On February 18, 2021 between hours 18:20-18:40 and a week after taking the second shot, patient lost balance (fainting) at home, fell, bruised a rib and fractured skull, causing subdural hematoma (bleeding outside of the brain). Bleeding stopped and several CT scans were performed. Under medical supervision, an anticoagulant medication was stopped to allow for healing. On February 20, 2021, moved from ICU to regular hospital room and on February 23 moved to another hospital for intense rehabilitation. Within days a thrombus developed causing a minor Cerebrovascular Accident, which was immediately identified by a medical doctor and nursing staff. On March 2, 2021 at 10:30 am moved to a Medical Center for further treatment. An endovascular thrombectomy for the removal of a thrombus was performed by a doctor. After recovery in the Neurosciences Critical Care ICU, under amazing care by the doctors, further thrombi developed on patient's lungs and around the bowel. Patient expired at 8:01 on March 4, 2021 due to Ischemic Complications of Thrombi/Thromboemoli.
COVID19 VACCINE	PFIZER\BIONTECH	1207792-1	50-59 years	7 days	Blood clotting resulting in blockage of LAD artery, precipitating an Myocardial Infarction.
COVID19 VACCINE	PFIZER\BIONTECH	1208543-1	30-39 years	7 days	Chest and back pain - pulmonary embolism, overnight hospital stay, blood thinner
COVID19 VACCINE	PFIZER\BIONTECH	1208641-1	65+ years	7 days	1 week after receiving the second dose of the Pfizer vaccine, started to feel short of breath with chest pain, a week later showed up to the hospital with extensive bilateral PEs and new onset A. fib. Physician can not determine the etiology behind the PEs, but cannot find any malignancy. Referred patient to pulmonology and hematology for further work-up. Physician feels that this could be an adverse reaction to the Pfizer vaccine Heparin drip for pulmonary emboli 4/8
COVID19 VACCINE	PFIZER\BIONTECH	1210386-1	40-49 years	7 days	Shortness of breath and chest pain 4/9/21 Went to ER on 4/9/21 Diagnosed with Multiple Pulmonary Embolisms in both lungs; transferred via ambulance as medical emergency to another hospital for treatment Released from hospital on 4/11/21 and currently under treatment
COVID19 VACCINE	PFIZER\BIONTECH	1212990-1	18-29 years	7 days	Fainted on April 9, waking to racing heart and shortness of breath. Chest pain and shortness of breath persisted. Visited Emergency Room evening of April 11. Multiple tests revealed diagnosis of pulmonary embolism. Was immediately transferred to hospital early April 12. Received blood thinning treatment and catheter operation. Discharged April 15, with prescription of Eliquis for continued blood thinning.
COVID19 VACCINE	PFIZER\BIONTECH	1216042-1	40-49 years	7 days	Swelling left leg. Femoral vein DVT identified on ultrasound on April 5, 2021 (partially occluded clot). hematologist switched me from Eliquis to starter pack of Xarelto.
COVID19 VACCINE	PFIZER\BIONTECH	1218835-1	60-64 years	7 days	CTA showed extensive bilateral PE involving R and L-pulmonary arteries with extension into lobar, segmental and subsegmental branches with questionable heart strain. LE US showed L-DVT in L-femoral vein, popliteal vein, posterior tibial veins, gastrocnemius vein. He denies any prior COVID diagnosis and reports 2nd dose of Pfizer vaccine on 3/31. Patient treated with heparin infusion and subsequently discharged on xarelto. No urgent mechanical thrombectomy or catheter thrombolysis was done.
COVID19 VACCINE	PFIZER\BIONTECH	1224926-1	Unknown	7 days	DVT; PE; This is a spontaneous report from a contactable consumer (patient). This adult male patient of unspecified age received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 27Mar2021, lot EP6955, in right arm, for COVID-19 immunization. No other vaccine was received in 4 weeks. Medical history and concomitant medications were not reported. On 03Apr2021 the patient experienced DVT and PE. The events resulted in emergency room/department or urgent care, life threatening illness (immediate risk of death from the event). Events treatment included dabigatran (PRADAXA). The events were resolving at the time of report. COVID was not tested post vaccination.

COVID19 VACCINE	PFIZER\BIONTECH	1227284-1	65+ years	7 days	She almost died from pulmonary edema; Lungs have blood clots in them; This is a spontaneous report from a contactable consumer (patient's husband). 74-year-old female patient received BNT162B2 (Pfizer-BioNTech COVID-19 mRNA vaccine), dose 2 intramuscular, administered in left upper arm muscle at age 74 years on 30Mar2021 (Batch/Lot Number: EP6955) as single dose, for COVID-19 immunisation. The patient medical history was reported as no. There were no concomitant medications. The patient historically took the first shot of BNT162B2 on an unspecified date for COVID-19 immunisation. It was reported that the patient took the shot of second dose of Pfizer BioNTech COVID Vaccine (Lot number: EP6955) shot on 30Mar2021 in her left upper arm muscle. Patient was in the hospital at the time of reporting hanging on to life. Patient got pulmonary edema and she almost died, her lungs are, have blood clots in them from 06Apr2021 then she went to the hospital on 07Apr2021, has to stay in the hospital for 4 days. Patient was not experiencing symptoms anymore, she has had blood thinners they administered blood thinners (treatment), she was improving. She has to stay 2 more days in the hospital taking the blood thinners. Laboratory test was done on 08Apr2021 which is in the hospital where she almost died. Vaccine was administered at a hospital. Patient was recovering at the time of report.
COVID19 VACCINE	PFIZER\BIONTECH	1230389-1	65+ years	7 days	High fever, severe night sweats, blood clots in lungs
COVID19 VACCINE	PFIZER\BIONTECH	1269503-1	60-64 years	7 days	Blood clots in colon; 2nd dose 07Jan2021; This is a spontaneous report from a contactable other hcp (patient). A 61-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19), second dose at the age of 61-years-old via an unspecified route of administration, administered in arm left on 07Jan2021 (Batch/Lot Number: Ek5730) as single dose for covid-19 immunisation. The patient medical history was not reported. The patient has no known allergies. Concomitant medication included unspecified medication. The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), administered in the left arm on 22Dec2020 (lot number: Ek5730) at the age of 61-years-old for covid-19 immunisation. The patient experienced blood clots in colon on 14Jan2021. It was noted that the patient received the second dose on 07Jan2021. The patient was hospitalized for blood clots in colon for 30 days. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 21Jan2021. Therapeutic measures were taken as a result of blood clots in colon which included surgery. The patient was recovering from the event.; Sender's Comments: Based on event-vaccine chronological association a causal relationship between event blood clots in colon and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), cannot be completely excluded. . The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1291181-1	Unknown	7 days	left jugular left vein thrombosis; This is a spontaneous report from a contactable consumer physician (reporting for herself). This 35- year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE Lot number: EN6208), via an unspecified route of administration, on 12Apr2021 as a single dose for COVID-19 vaccination. No relevant medical history and concomitant medications was reported. States: no past medical history of blood clots, not on birth control pills and had two children with no issues. She received her first dose of the Pfizer BioNTech Covid 19 vaccine on 12Apr2021, she developed symptoms 5 days later, and then went to the ER and was diagnosed with a left jugular left vein thrombosis on 19Apr2021. Patient was released on Xarelto starter pack and then will be on Xarelto 20mg. The clinical outcome of the events was unknown. Information about the Lot/batch number has been requested.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Jugular vein thrombosis cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID19 VACCINE	JANSSSEN	1172945-1	18-29 years	8 days	Admitted 4/3 with a cerebral sinus venous thrombosis, portal vein thrombosis and pulmonary embolus. Pt received covid vaccine 3/18. Symptoms began 3/26 which started with chills and body aches. Then on 3/27- developed a severe headache in the back of her head with associated nausea. On 3/28 she had the most severe headache on the right side of her head. She was vomiting from 3/28-3/30. On 3/30 she went to the ER for evaluation of her severe headache. She was given a ""migraine cocktail"", no imaging was completed and she was sent home. Appetite improved on 3/31 and she had a small headache relieved with Excedrin. Then on 4/1-4/2 she had severe bloating , abdominal pain and fever of 100.4. She had been visiting her mom for the holidays and came to the ER. Imaging revealed cerebral sinus venous thrombosis, portal vein thrombosis and pulmonary embolus. She was started on a heparin drip and brought to ICU for monitoring.. She is not on any oral contraceptives and does not have any family history of clotting disorders.""
COVID19 VACCINE	JANSSSEN	1202639-1	50-59 years	8 days	Develop a blood clot lost vision in left eye due to stroke. I?m still in the hospital. I am 50 and had a stroke a week at getting that vaccine TPA shot. Given. Clot buster
COVID19 VACCINE	JANSSSEN	1204433-1	30-39 years	8 days	Cramp behind knee. Treatment included Asa, compression stocking and warm compress
COVID19 VACCINE	JANSSSEN	1204438-1	30-39 years	8 days	patient developed leg pains bilaterally. went to emergency room and diagnosed with DVT in right leg
COVID19 VACCINE	JANSSSEN	1204459-1	65+ years	8 days	blood clot in left ear
COVID19 VACCINE	JANSSSEN	1207539-1	40-49 years	8 days	Chills/shaking began approximately 8 hours after injection. Other symptoms of an achy upper body, temperature of 103.1, and nausea came shortly after initial symptoms (within 1 hr.). In the middle of the night, I began heavily sweating (something I have never experienced). I was drenched with sweat and needed to change in the middle of the night. Absolutely no energy and a horrible headache. 24 hrs. after the injection I no longer had a high fever. However, consistently for a week, every day, I had at least one symptom (headache, nausea, chills, or lack of energy) at some point throughout the day. When I received the injection, I was on day 2 of my period. It ended one day later than normal. However, what was not normal was that on 4/3/21, I began to bleed again. I passed 2 clots and had spotting for an additional 5 days. This is in no way normal to my cycle.
COVID19 VACCINE	JANSSSEN	1208303-1	50-59 years	8 days	Pulmonary Embolism- left lung. Eliquis 5mg tablet medication once in morning and once at night
COVID19 VACCINE	JANSSSEN	1210378-1	65+ years	8 days	Massive Pulmonary embolism with evidence of right heart strain, acute hypoxic respiratory failure, Axute DVT of right lower extremity. No obvious known provoking factors
COVID19 VACCINE	JANSSSEN	1211952-1	50-59 years	8 days	pulmonary embolisms
COVID19 VACCINE	JANSSSEN	1213298-1	65+ years	8 days	I started having migraine headaches on 3-19-2021 , this lasted for 3 days. On 3-23 started coughing up blood , that progressively became worse. Went to emergency room and was admitted CAT scan of lungs showed that I had 3 blood clots.
COVID19 VACCINE	JANSSSEN	1213388-1	30-39 years	8 days	Patient presenting with right calf pain that began on 4/10/2021. Diagnosed on 04/15/2021 with right lower extremity DVT.
COVID19 VACCINE	JANSSSEN	1215945-1	65+ years	8 days	Bilateral Pulmonary Emboli
COVID19 VACCINE	JANSSSEN	1216439-1	50-59 years	8 days	Severe headache 2 days in duration with associated nausea and vomiting, admitted with hypertensive urgency, Cerebral Venous Sinus Thrombosis diagnosed via MRV and CTA
COVID19 VACCINE	JANSSSEN	1218930-1	65+ years	8 days	NA Lung cancer - developed a cerebral thrombosis
COVID19 VACCINE	JANSSSEN	1220723-1	30-39 years	8 days	36 year old male with hx of hypertension , asthma , schizophrenia . he recieved Janssen vaccine on 4/6/2021. he started to fell unwell on 4/14 and on 4/15 he was found by his father unresponsive then sent to the hospital. Pt was diagnosed with massive pulmonary embolism, severe shock, acute renal failure ,Diabetic ketoacidosis , hyperglycemic hyperosmolar nonketotic coma, acute respiratory failure, patient expried from massive pulmonary embolism within 48 hours after admission.
COVID19 VACCINE	JANSSSEN	1221298-1	50-59 years	8 days	Large saddle pulmonary embolism. No DVT. Patient stable, hospitalized. Form competed upon admission, unknown duration of hospitalization at this time

COVID19 VACCINE	JANSEN	1223301-1	50-59 years	8 days	Patient reports tear in esophagus on 3/24/21 in the evening whenever she felt sick to her stomach. She did not feel well, drank one beer, and ate a packet of tuna. She continued to not feel well and felt the food did not go down correctly, so she reached into her throat and noticed blood. She called her doctor and the doctor recommended monitoring for increased bleeding. Later that night, she reports not feeling well again, made herself throw up, and noticed the vomit was all blood. The patient then called 9-1-1, and presents to the hospital. During the hospital visit she noticed that she saw 'blood clots about the size of a quarter' when she went to the bathroom. Patient reports the hospital gave her 4 pints of blood, 4 bags of 'yellow stuff' (patient assumes its plasma), protonix, antibiotics, and NS. Patient was in the ICU and reports being in the hospital for about 5 days total, whenever the doctor recommended being put on hospice. The patient did want to be put on hospice and wants to be treated, so she contacted her heart doctor and is waiting on an appointment with him on the 28th of April. Patient reports that doctor told her that she 'needs a new heart', but that she is not a good candidate, and that the Dr. told her this just a day or two ago. Patient reports that she did not know it was a tear in her throat (esophagus) until they ""stuck a scope down there"". ""
COVID19 VACCINE	JANSEN	1225799-1	50-59 years	8 days	4/11/2021 830PM I NOTICED MOISTURE IN MY UNDERWEAR. WENT INTO BATHROOM , PANTIES BLOODED, BRIGHT RED AND A QUARTER SIZED CLOT WAS INTHE TOILET. I SUFFERED NO PAIN. HOWEVER I HAD A TOTAL HYSTERECTOMY IN 1997, AND SHOULD NOT HAVE ANY BLEEDING WHATSOEVER. TOOK A SHOWER, ADVISED MY HUSBAND OF THE INCIDENT. WENT TO BED , 230AM 4/12/2021 SAME THING HAPPENS, ONLY NOW I AM WIPING BRIGHT RED BLOOD AND I FELT A LARGER SIZED CLOT LEAVE MY BODY. I WENT TO THE ER IMMEDIATELY.
COVID19 VACCINE	JANSEN	1226242-1	50-59 years	8 days	Eight days after receiving the vaccine, my wife developed shortness of breath, headache, fatigue, and unusual vision problems. She was taken to the emergency room on 4/15 where she underwent a battery of tests (see details below). She was admitted to the hospital (where she currently is) and was diagnosed with blood clots in the lungs and two strokes in the area of the brain that affects vision. She then underwent ultrasound tests of her legs and carotid artery, which were negative for signs of blood clots. Although my wife's symptoms are different than the symptoms of others that led to the vaccine pause, her doctors strongly encouraged us to report it to the VAERS. My wife had no underlying or pre existing conditions that would lead to blood clots in her lungs, and stroke. After extensive testing there is no evidence that the blood clots in her lungs as well as the clot/clots that went to her brain initiated in her legs. They believe that some sort of ""event"" would have had to happen to cause these blood clots, and the only unusual thing in the time frame of this condition is the vaccine. As I mentioned earlier, my wife is still hospitalized.""
COVID19 VACCINE	JANSEN	1228883-1	65+ years	8 days	Painful lump on inner aspect of R calf. Swelling on R lower leg along with diffuse pink skin. Developed 8 days post vaccination. Treated with rivaroxaban started.
COVID19 VACCINE	JANSEN	1230771-1	50-59 years	8 days	Deep Vein Thrombosis in lower right leg
COVID19 VACCINE	JANSEN	1232655-1	50-59 years	8 days	patients PCP office called to inform us that patient was positive for a DVT today. She was calling to inform us of the adverse event following her vaccination 04/12/2021. Blood clots were the reason that was reported for this vaccine to be pulled from the market the very next day 04/13/2021. Called the office back and left message with them to report as well since they have lab work and other patient information
COVID19 VACCINE	JANSEN	1236988-1	50-59 years	8 days	Acute deep vein thrombosis (DVT) of popliteal vein of left lower extremity
COVID19 VACCINE	JANSEN	1238962-1	65+ years	8 days	PATIENT HOSPITALIZED ON 4/18. ON 4/19- CT SCAN WITH CONTRAST- SMALL PULMONARY EMBOLISM RT LOWER LOBE
COVID19 VACCINE	JANSEN	1241957-1	50-59 years	8 days	Thrombosed Hemorrhoid (blood clot). Rapid onset of initial pain. Still experiencing pain.
COVID19 VACCINE	JANSEN	1244775-1	50-59 years	8 days	Went emergency after noticing one of my veins had turned red and was hardening. Vein pulsing in left leg. Emergency room doctor diagnosed ""superficial thrombophlebitis."" The pulsing in lower leg (calf) continues and in elbow and wrist joints. The pain is not an issue. I've been feeling a bit of but most of my discomfort has been anxiety about what's going to happen next and what are the throbbing. The vein is no longer red, is slightly hard, pain is a 1 on scale of 10. Doctors have not contacted me since the evening after I was seen and I reported to them I felt better than I did at the hospital.""

COVID19 VACCINE	JANSSEN	1244816-1	30-39 years	8 days	Patient complained of fever and chills on 4/18. Patient continued to have symptoms, suspected to be acute frontal sinusitis. On 4/21, patient complained of bilateral leg heaviness, felt weighed down, difficult to walk, no weakness, swelling, or redness. Patient elevated legs and felt better on 4/22. Patient later presented to the ED with acute mental status changes. Patient fell at home and had a seizure according to family. Patient is currently intubated and critically ill.
COVID19 VACCINE	JANSSEN	1247817-1	50-59 years	8 days	52 yo female received J&J COVID-19 vaccination on 3/10. On 3/18, she presented to the ED with chief complaint of SOB and anemia. CT confirms bilateral submassive PE seen in segmental and subsegmental lobes. Symptomatic with tachypnea, pleuritic CP, tachycardia. Patient has history of PE 3 years ago as well, and was on warfarin for 6 months. Only family history of clots is elderly grandmother with DVT's. No sudden death in family. Age-appropriate cancer screening up to date. Patient is wheelchair bound and was dehydrated 2/2 gastroenteritis which made her high risk for VTE. Less likely due to hypercoagulable disorder. At discharge, she is hemodynamically stable...Tachypnea and pleuritic chest pain resolved. Myeloproliferative neoplasm panel negative. She was started on apixaban (will finish loading doses 3/26, and continue 5mg BID indefinitely). Will be referred to hematology as outpatient for PE + anemia.
COVID19 VACCINE	JANSSEN	1251202-1	40-49 years	8 days	Events: Vaccine was given on 3/19/21; Hysterectomy on 3/25/21; blood clots diagnosed on 3/30/21 Left forearm was swollen, with a light reddish tint to it, and tender. After getting an ultra sound on my forearm a DVT was found and I was sent to the emergency room. I then had a CT scan done of my chest and it was discovered I had several pulmonary emboli. I was admitted to the hospital and put on a heparin drip. I am currently taking Eliquis and will be following up with a pulmonologist and a hematologist in a week or two.
COVID19 VACCINE	JANSSEN	1260272-1	50-59 years	8 days	Soreness & lump in left lower thigh size of tic tac Swollen and sore left foot Diagnosed with ultrasound as superficial blood clot Heat applied and aspirin Still swollen
COVID19 VACCINE	JANSSEN	1262401-1	60-64 years	8 days	Throbbing pain at injection site and entire arm. Unable to move up without assistance. Pain grew more and more intense. Went to urgent care on unspecified date. NP examined me and discovered a lump in my arm. Both the lump and the vaccination site hurt when she pressed on them. She prescribed predone and gave me a work order for a vascular ultrasound to be performed on my left arm. I went on unspecified date for the scan. It was discovered that a DVT blood clot had formed in my brachial vein in the left arm. I was then prescribed eliquis, 20 mg a day for 7 days and told not to take the predesone. NP called my pcip, his office immediately called me and asked me to come in as they are concerned about the high dosage of the eliquis.
COVID19 VACCINE	JANSSEN	1263645-1	40-49 years	8 days	Headache from 4/14/21 to 4/24/21, tonic-clonic seizure on 4/24/24 admitted to hospital on 4/24/24
COVID19 VACCINE	JANSSEN	1268089-1	50-59 years	8 days	Two blood clots in right leg below the knee, calf pain, swelling of lower leg and foot, painful to walk
COVID19 VACCINE	JANSSEN	1292494-1	50-59 years	8 days	Pt developed calf pain ~ 1-2 week after COVID vaccine. Diagnosed with DVT/PE on 5/6 with platelet count decreased from baseline at 92,000.
COVID19 VACCINE	MODERNA	0947660-1	50-59 years	8 days	I developed a left Internal Jugular vein thrombosis with supraclavicular inflammation and pain. I was diagnosed by CT scan and Doppler ultrasound. I have been started on Xarelto 1/11/2020. Symptoms were localized and are slowly resolving.
COVID19 VACCINE	MODERNA	0969230-1	60-64 years	8 days	Developed blood clot in left leg (DVT)
COVID19 VACCINE	MODERNA	1064684-1	65+ years	8 days	Deep vein thrombosis (DVT) of left lower extremity She reported swelling of her left leg and was seen at Family Medicine Urgent Care on 2/19/2021 and was diagnoses with a thrombosis of the left popliteal vein. She was treated with Xarelto for anticoagulation and compression stockings. Her treatment course was uncomplicated when I saw the patient at follow up and was made aware of her condition at her appointment with me on 3/1/2021.
COVID19 VACCINE	MODERNA	1071396-1	65+ years	8 days	ER admission on February 27th, discharged with a diagnosis of Bilateral Pulmonary Embolism and DVT of lower limb
COVID19 VACCINE	MODERNA	1095915-1	18-29 years	8 days	I got a blood clot in my left leg, as well as numerous blood clots in both my lungs. I have never had a blood clot before, and my family does not have a history of them.

COVID19 VACCINE	MODERNA	1098587-1	65+ years	8 days	shortness of breath, pain in chest increasingly more severe as time went on. Noticed shortness of breath about 12 days after the vaccine was given. I am a 2 mile a day walker and very healthy. It was below freezing and I attributed the shortness of breath to weather. I went to an ER on March 8, 2021 after realizing symptoms were worse. I was admitted with Pulmonary embolism in both lungs and pneumonia in both lungs. The hospitalist could not give me a reason why this happened. He encouraged me to report this incident. You would need to contact him for tests and such. I am a patient. I live where medical help is limited. The vaccine was administered at a clinic but the ER I went to was a different system.
COVID19 VACCINE	MODERNA	1098953-1	65+ years	8 days	KEY POINTS Had the first dose of the Moderna vaccine on Mon. Jan 11. Symptoms started Tuesday, January 19, 2021 1st hospitalization, January 27, 2021 o Discharged, January 29, 2021 o Diagnosis: High leukocytes, inflammation. Diagnosis, acute pancreatitis. 2nd hospitalization, February 2, 2021. o Discharged February 4, 2021. o Diagnosis: Diagnosis, Deep vein thrombosis (DVT) of popliteal vein and pneumonia Details in notes section. NOTE This is an updated and correctly filed version of a form that I attempted to email to the regulatory authority. No evidence that it went through. Use this version if you have the earlier version. DETAILED DESCRIPTION OF EVENTS AFTER VACCINATION PROGRESSION OF SYMPTOMS TUES. JAN 19: At night, felt like hunger pangs ° but not really relieved by eating. In the morning tried 2 Tums. Had temporary relief for about an hour. Had symptoms for the last three days. Chronic, varied between almost negligible to mildly annoying. Bowel habits usually very regular. WED. JAN 20. Had major bowel movements in the middle of the night THUR. JAN 21. Had major bowel movements in the middle of the night FRI. JAN 22. Extremely mild feelings of bloatedness over the last couple of weeks (0.5 on 1 to 10). A slight loss of appetite, but did not interfere with eating. Sometimes slightly nauseous. (0.5 on 1 to 10) SAT. JAN 23. Extremely mild feelings of bloatedness over the last couple of weeks (0.5 on 1 to 10). A slight loss of appetite, but did not interfere with eating. Sometimes slightly nauseous. (0.5 on 1 to 10) SUN. JAN 24. Extremely mild feelings of bloatedness over the last couple of weeks (0.5 on 1 to 10). A slight loss of appetite, but did not interfere with eating. Sometimes slightly nauseous. (0.5 on 1 to 10) MON JAN 25. Extremely mild feelings of bloatedness over the last couple of weeks (0.5 on 1 to 10). A slight loss of appetite, but did not interfere with eating. Sometimes slightly nauseous. (0.5 on 1 to 10) TUES. JAN 26. Problems persisted and got worse. On Jan 26, Daughter GP suggested getting blood analysis to test for inflammation. WEDS, JAN. 27. Hospitalized. Findings: High leukocytes, inflammation. Diagnosis, acute pancreatitis. THURS. FRI. JAN 28. Hospitalized. FRI. Jan 29. Discharged. Wt 193 lbs! Usual, ~176-183. MONDAY FEB 2. Readmitted to hospital. Felt feverish, easy fatigue, bilateral stiffening of the calves, some edema. Diagnosis, DVT of popliteal vein and pneumonia. Given an iv bolus of a broad spectrum antibiotic. Started on Eliquis two 5mg pills twice a day for one week and the one tablet am and one pm. Given Lasix bolus and then started on 5 mg Lasix/day. Swallowing tests more or less OK WEDNESDAY FEB. 4. Discharged. MONDAY, MARCH 8, Check up with GP, Blood pressure 127/76. Lasix discontinued. THURSDAY, MARCH 11, Check up with GI doctor, Blood pressure consistently 150/90. Sent to adjacent cardiologist's office (next door). High BP reading confirmed and reconfirmed the next day. Dose of Metropolol succinate increased to 5 mg 2xday. Note 1: Still have the DVT. Note 2: Received 2nd dose of Moderna vaccine on Feb 11. Note 3: All medical records available either through hospital, GP or by contacting me. Note 4: This is not a crank report. I have had 50 years teaching and doing funded research in 3 medical schools rising to the rank of full Professor in each.
COVID19 VACCINE	MODERNA	1101916-1	40-49 years	8 days	Began having noticeable muscle pain in my chest in the first part of 2/2021. I continued to think it was just muscle pain. Symptoms worsened with severe sharp/stabbing pain with movement and breathing that radiated to my back. Went to the emergency room 3/7/2021. Dx of multiple small pulmonary artery webs that may represent sequela of pulmonary thromboembolism. There is also a 2 mm nodule in lower R lobe of lung. Eliquis dose increased to 10 mg BID x 7 days then decrease to 5 mg BID.
COVID19 VACCINE	MODERNA	1131580-1	65+ years	8 days	After second Moderna covid vaccine , 1 1/2 weeks after second vaccine I ended up with blood clots in right leg and right lung - hospital overnight stay. Outcome is not good thanks to the covid vaccine

COVID19 VACCINE	MODERNA	1148864-1	65+ years	8 days	Pt is a previously healthy 76 year old woman who received her covid vaccine 2 wks ago. She received Moderna vaccine on 3/8/21. On 3/16/21 She developed symptoms of fatigue, chills, body aches, decreased exercise tolerance. 3/19/21 exercised at YMCA as she does regularly. She was not able to do her usual level of activity and was only able to exercise low level for 10 minutes. Yesterday was very sob and after washing 2 windows had to lay down and rest. In my office the nurse rooming the pt noted the pt to be very winded and sob just ambulating from waiting room to the exam room. Pox was down to 89% and took a while to come up to 94%. Transferred to Hospital ED. DiagnosedDiagnosis: Acute hypoxic respiratory failure secondary to massive Pulmonary Emboli, DVT without known precipitating factors. pt without previous history of clotting disorder, no known neoplasm, no recent travel or sedentary period. unprovoked DVT with MASSIVE PE. patient did not have previous pulmonary disease. Additional information for Item 19: studies: PO Chest Final Result Stable chest. No new opacities are identified in this patient with known extensive bilateral pulmonary embolus. US Venous Duplex Lower Extremity Bilateral Final Result 1. Acute DVT involving the right popliteal and posterior tibial veins. 2. No acute DVT involving the left lower extremity. CT PE Protocol WITHOUT legs Final Result 1. Positive exam: Large-volume central pulmonary emboli seen in both main pulmonary arteries with extension bilaterally into all lobes. Dilated right heart chambers suggesting acute right heart strain. 2. Peripheral groundglass opacities in the right upper lobe may represent small area of pulmonary hemorrhage or developing infarct. Red Level 1 findings were entered into the system.   Actionable Findings system for documentation and communications on 3/22/2021 4:31 PM, Message ID 191499. 3. Pulmonary nodules in the right lower lobe measure up to 4 mm maximally. See below consensus guidelines. TTE - INTERPRETATION SUMMARY: Left ventricle is normal in size. There is normal left ventricular systolic function. The quantitative LVEF based on modified Simpson's method is 62%. There is asymmetric septal hypertrophy with maximal wall thickness of 1.3 cm. There is mild (grade I) diastolic dysfunction with normal left atrial pressure. Right ventricle is normal in size. There is normal right ventricular systolic function. No previous echocardiogram in Froedtert Health system for comparison.
COVID19 VACCINE	MODERNA	1152759-1	40-49 years	8 days	7 AM 3/25/2021 - Patient called out to husband from the bathroom where she experienced a syncopal event, then passed out. An ambulance was called and she was revived for a short period of time. She was taken to Hospital where she coded 3 times. She was then life-flighted to second Hospital. According to the hospital records, tests conducted over the course of several days determined that she had no neurological activity. Initial reports in the records indicate pulmonary embolism, cardiac and respiratory arrest. She was on life support for the remainder of her time. Organ donation is being pursued at present and results of this are pending at time of this report submission. Date of death is unknown until organ retrieval is accomplished. Family will be contacted in the next few days to ask further questions about any other kinds of vaccine-related reactions that may have happened more immediately to days after the vaccination on 3/17/2021. A co-worker thought that she had shortness of breath for 3-4 days before this critical event occurred on 3/25/2021.
COVID19 VACCINE	MODERNA	1152785-1	30-39 years	8 days	Experienced excruciating lower abdominal pain starting on March 9th, frequent bowel movements (at times diarrhea). Have had frequent painful bowel movements since March 9th. Then on March 27th experienced extreme lower abdominal pain with bleeding and clotting in urine. Went to the ER, WBC was 17.2 and Catscan showed inflammation in colon and diagnosed with Mild to Moderate Acute Pancolitis.
COVID19 VACCINE	MODERNA	1196999-1	40-49 years	8 days	on 4-6, developed upper thoracic back pain. went to ED, Dx with pumonary embolism.
COVID19 VACCINE	MODERNA	1200624-1	65+ years	8 days	You got the vaccine, had no reaction initially. Arm never got sore, nothing at all. Approximately 8 days later he was watching TV, woke up, got up to use the restroom and walked about 40' to get to the bathroom and was breathing so hard that he had to sit down. He went to go back to the couch and was exhausted, got light headed and fell on the floor. He got his wife up, got her dressed and he went to the ER. They said he had a pulmonary embolism and kept him in ICU for 5 days. He has since been okay, been on Eliquis since he has been discharged. Admitted on 2/18/21 and discharged on 2/22/21.

COVID19 VACCINE	MODERNA	1212396-1	18-29 years	8 days	Admitted 4/13/21at 39 weeks for planned primary low transverse Cesarean Section due to velamentous cord insertion. CS was uncomplicated. APGAARs 8 and 9, weight 6lbs, 10oz. On 4/14/21 patient got up to take a shower. After her shower she felt like her left leg felt ?tight? and was more red in appearance. She denied pain. She reports that leg got more swollen at one point in pregnancy as well. OBMD in to assess patient. Vascular US ordered and revealed extensive DVT from calf to groin on the left. Patient received her 2nd dose of Moderna 4/6/21.
COVID19 VACCINE	MODERNA	1245380-1	60-64 years	8 days	Patient urinated blood clot in urine; Patient urinated blood in urine; This spontaneous case was reported by a consumer and describes the occurrence of HAEMORRHAGE URINARY TRACT (Patient urinated blood clot in urine) in a 64-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Lymphoma. Concomitant products included ACALABRUTINIB (CALQUENCE) for Lymphoma, CYANOCOBALAMIN (VITAMIN B-12), CALCIUM and FOLIC ACID for an unknown indication. On 01-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .5 ml. On 09-Apr-2021, the patient experienced HAEMORRHAGE URINARY TRACT (Patient urinated blood clot in urine) (seriousness criterion medically significant) and HAEMATURIA (Patient urinated blood in urine). On 10-Apr-2021, HAEMORRHAGE URINARY TRACT (Patient urinated blood clot in urine) and HAEMATURIA (Patient urinated blood in urine) had resolved. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient recovered (clarified as the patient's urine was clear and did not have blood clots) on 10 Apr 2021. Patient self treated by drinking lots and lots of fluids (not further clarified). Company comment: Based on the current available information and the temporal association between the product use and the start sate of the events a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and the temporal association between the product use and the start sate of the events a causal relationship cannot be excluded.

COVID19 VACCINE	MODERNA	1245454-1	40-49 years	8 days	<p>Small amount of blood clots; Potassium levels dropped; Increased hypertension; dizziness; Arm pain from her elbow to shoulder; Shortness of breath; Blood pressure increased; fatigue; chills; Hear arm was hot to touch; Itchiness; Red circle near injection site the size of a quarter; not to take the second dose; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Small amount of blood clots) and HYPOKALAEMIA (Potassium levels dropped) in a 44-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 026A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse reaction. On 15-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Mar-2021, the patient experienced VACCINATION SITE ERYTHEMA (Red circle near injection site the size of a quarter). On 24-Mar-2021, the patient experienced VACCINATION SITE WARMTH (Hear arm was hot to touch) and VACCINATION SITE PRURITUS (Itchiness). On 25-Mar-2021, the patient experienced PAIN IN EXTREMITY (Arm pain from her elbow to shoulder), DYSPNOEA (Shortness of breath), BLOOD PRESSURE INCREASED (Blood pressure increased), DIZZINESS (dizziness), FATIGUE (fatigue) and CHILLS (chills). On 01-Apr-2021, the patient experienced THROMBOSIS (Small amount of blood clots) (seriousness criterion medically significant), HYPOKALAEMIA (Potassium levels dropped) (seriousness criterion medically significant) and HYPERTENSION (Increased hypertension). On an unknown date, the patient experienced PRODUCT DOSE OMISSION ISSUE (not to take the second dose). At the time of the report, THROMBOSIS (Small amount of blood clots), HYPOKALAEMIA (Potassium levels dropped), PAIN IN EXTREMITY (Arm pain from her elbow to shoulder), DYSPNOEA (Shortness of breath), BLOOD PRESSURE INCREASED (Blood pressure increased), HYPERTENSION (Increased hypertension), VACCINATION SITE WARMTH (Hear arm was hot to touch), DIZZINESS (dizziness), VACCINATION SITE PRURITUS (Itchiness), FATIGUE (fatigue), VACCINATION SITE ERYTHEMA (Red circle near injection site the size of a quarter) and CHILLS (chills) outcome was unknown and PRODUCT DOSE OMISSION ISSUE (not to take the second dose) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. On 01-Apr-2021 patient went to the ER for 2 hours. The HCP at the ER stated she had increased hypertension, potassium levels dropped and there was a small amount of blood clots. Her primary care physician said not to take the second dose. Patient inquired about what she can do to manage her symptoms. Concomitant drugs were not reported. Treatment information was not provided. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, Further information is requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, Further information is requested.</p>
COVID19 VACCINE	PFIZER\BIONTECH	0968364-1	60-64 years	8 days	Pulmonary embolus developed 8 days after second injection. No previous history of vascular events. No known risk factors.
COVID19 VACCINE	PFIZER\BIONTECH	0992022-1	60-64 years	8 days	Superficial blood clot in right medial knee area. Aspirin, elevate right leg, compression and heat.
COVID19 VACCINE	PFIZER\BIONTECH	0992245-1	50-59 years	8 days	Superficial and deep vein thrombosis was diagnosed on 27th of January. Symptoms had been going on for around 2 weeks.

COVID19 VACCINE	PFIZER\BIONTECH	1015660-1	40-49 years	8 days	swollen left calf that was DVT, deep vein thrombosis; This is a spontaneous report from a contactable Other Health Professional. A 49-year-old male patient received 2nd dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot: EL3248), via an unspecified route of administration on 11Jan2021 at single dose on left arm for COVID-19 immunisation. Medical history included hypothyroidism and high cholesterol. Patient had no known allergy. No COVID prior vaccination. No COVID tested post vaccination. Historical vaccine included 1st dose of bnt162b2 (lot: EK5730) via intramuscular on 23Dec2020 at 15:30 at single dose on left arm for COVID-19 immunisation. Concomitant medication included levothyroxine and atorvastatin. 1 week after receiving the 2nd dose, patient woke up with a swollen left calf. Ultrasound the same day (19Jan2021) showed that was DVT, deep vein thrombosis. Patient started taking apixaban (ELIQUIS) (blood thinner) the same day. Event resulted in doctor or other healthcare professional office/clinic visit. Outcome of the event was resolving. No follow-up attempts are possible. No further information is expected.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported event cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1041487-1	65+ years	8 days	Patient developed shortness of breath and irregular heart beat 8 days after receiving immunization. Presented to the Clinic and was sent to the Emergency Department for evaluation. Admitted for PE, NSTEMI, and afib with RVR 2/11/21. Discharged to home 2/12/21.
COVID19 VACCINE	PFIZER\BIONTECH	1049035-1	65+ years	8 days	On Sunday, February 21 at 07:42 AM I received a call from patient advising me she had called for an ambulance, she was awoken from her sleep with a rapid heart beat and was also suffering from shortness of breath. Patient was taken to Hospital where she was admitted due to a Pulmonary Embolism, a small clot was found in her lung.
COVID19 VACCINE	PFIZER\BIONTECH	1049728-1	65+ years	8 days	Patient is positive for COVID-19 and being admitted to the hospital. Patient received dose 1 of the vaccine on 2/11/21 and began feeling ill several days before presentation to the ED. He is unable to pinpoint an exact date but states it has been a few days that he has felt unwell. Presentation to the ED was on 2/23/21 and his oxygen saturation on presentation was in the 80s with mild confusion. Patient is requiring supplementary oxygen. The patient is receiving dexamethasone.
COVID19 VACCINE	PFIZER\BIONTECH	1080222-1	65+ years	8 days	Pulmonary embolism; Multiple clots in his lungs; Shortness of breath; This is a spontaneous report from a contactable consumer (patient wife). A 72-years-old male patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number unknown and expiration date not reported), via an unspecified route of administration on 10Feb2021 at a single dose for Covid-19 immunization. The patient medical history was not reported. Concomitant medication included levothyroxine. The patient previously took first dose of bnt162b2 (EL8982) on 19Jan2021. The reporter (wife) stated that she and her husband both took the Covid vaccine. The patient (husband) is the one who have the adverse reactions. On 19Jan2021, she and her husband had the first shot, the Pfizer Covid shot. On 10Feb2021, they had the second shot. Just today she picked her husband from the hospital, they dismissed him for today because on 18Feb2021, she had to take him to emergency room because he had pulmonary embolism. He has multiple clots in his lungs. This is nothing that they dealt before with him. The reporter is afraid that it might be related to have taken the vaccine. Reporter stated that when she took him to the emergency room, it was 18Feb2021. Now he had a little shortness of breath for few days before the 18th but they didn't realize that he was having a big problem. He fully developed this on 18Feb2021. The reason for hospitalization was pulmonary embolism and blood clots in his lungs. He is little bit slow like the reporter said she got him to the hospital where he stayed 3 days she guess with pulmonary embolism, from 18Feb2021 to 21Feb2021. He had lot a of lab work while he was in hospital on these days the wife described. He had blood work, Echocardiogram, CAT scan, Ultrasounds, Chest X-ray, Covid rapid test, they haven't got back the result yet. Outcome of the events was unknown.
COVID19 VACCINE	PFIZER\BIONTECH	1093401-1	65+ years	8 days	Right leg pain and swelling 8 days after second dose. Started on Eliquis in the ER following positive ultrasound exam.
COVID19 VACCINE	PFIZER\BIONTECH	1144362-1	60-64 years	8 days	1 week later, left calf pain, SOB

COVID19 VACCINE	PFIZER\BIONTECH	1147851-1	65+ years	8 days	Patient presented 8 days after her vaccine with fevers and lethargy. She subsequently developed DVT, PE, and severe thrombocytopenia consistent with ITP. She has also developed encephalitis.
COVID19 VACCINE	PFIZER\BIONTECH	1157795-1	65+ years	8 days	bilateral PEs - diagnosed 4/1/21
COVID19 VACCINE	PFIZER\BIONTECH	1187004-1	50-59 years	8 days	53 yo female with a history of PE 12 years prior after 22 hour flight received her first dose of Pfizer BioNTech vaccine on March 20. She tolerated the vaccine without report of systemic adverse events including headache, fevers, chills, myalgia, malaise or nausea. Eight days later (March 28) she experienced light-headedness and uneasiness reminiscent of her prior PE prompting her to visit the emergency room. Per patient D-Dimer was extremely elevated and PE protocol CT chest with IV contrast diagnosed multiple pulmonary emboli. This time, no immediate precipitating factors were identified. She has normal BMI (23), exercises regularly, is a never-smoker. She was placed on therapeutic lovenox 80mg BID. She indicated that is undergoing a workup for a hypercoagulable state and was told she may have antiphospholipid antibody syndrome, although the data and records to support this evaluation are not available for confirmation by undersigned.
COVID19 VACCINE	PFIZER\BIONTECH	1205919-1	18-29 years	8 days	Approximately 7-10 days or so after receiving the first dose of the pfizer Covid vaccine I started to develop this red, nodule-like, painful ""rash"" on both of my forearms. Not only the left arm where the vaccine was administered. This did not go away after a couple of days, and I was instructed by a physician to being taking Benadryl. This appeared to alleviate the symptoms (no visible red nodules anymore) 4-5 days prior to my second dose, so I stopped the medication and presumed it was done. Then, within 4-5 hours of receiving my second Pfizer covid vaccine, I broke out into the same red, painful, nodule-like ""rash"" along both of my forearms. This time was worse than the previous reaction. I was instructed to take Allegra at the time by a physician, which I did for approximately 4 weeks. This seemed to get rid of the symptoms I was experiencing, and I could not visualize the nodules on my forearms anymore. However, after approximately 2 weeks, I noticed a painful and swollen vein in my right forearm, opposite arm to the one I received the vaccine in. I did not think much of it at the time, since I had no other associated symptoms. Then, over the next couple of weeks, it appeared to become more swollen and painful. Also, I saw another swollen vein near my knee. On April 6, I had labs drawn and CBC, CMP, TSH, and ESR came back normal, but the CRP was elevated. Thus, I was instructed to begin aspirin 325mg, which I took for 4 days beginning April 8th and ending April 12th. On April 13th, an official ultrasound confirmed a DVT in my right popliteal vein, a superficial thrombus in my proximal great saphenous vein, and a superficial thrombus in my right forearm where the pain originated from weeks prior. The initial presumption at this time is that the clots are vaccine-related, but could be linked to an underlying blood disorder that was triggered by the vaccine. Blood hyper coagulation labs have not yet come back. I was initiated on Eliquis starting April 12th for the DVT.""
COVID19 VACCINE	PFIZER\BIONTECH	1210932-1	65+ years	8 days	Hemorrhagic stroke resulting in paralysis of L side of body DVT in L calf
COVID19 VACCINE	PFIZER\BIONTECH	1210966-1	65+ years	8 days	My mother was found unconscious on the kitchen floor. She was taken to the hospital. She had different test including a Cardiac stress test and it was found to be okay. However, my mother developed a blood clot in her left leg. She still been under medical observation in the hospital.
COVID19 VACCINE	PFIZER\BIONTECH	1219434-1	50-59 years	8 days	Pt had her second COVID vaccine on March 27th 2021, On April 4th 2021, the patient went to the ER due to shortness of breath, dizziness, and racing heart rate. After patient participated in physical activity she had to lay down afterwards due to the shortness of breath. Pt spent 2 days in the hospital after being diagnosed with bilateral pulmonary embolisms. Pt was started on Xarelto and was discharged from the hospital on April 6th.

COVID19 VACCINE	PFIZER\BIONTECH	1224898-1	65+ years	8 days	Stroke due to a large blood clot to the brain; Stroke due to a large blood clot to the brain; Widespread blood clots in both of her arms; This is a spontaneous report from a contactable consumer (daughter). A 67-year-old female patient received the 2nd single dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration, in the left arm, on 17Mar2021 (at the age of 67 years old, not pregnant at time of vaccination) (Lot number was unavailable since unable to locate or read the details), for COVID-19 immunisation. The patient's medical history included ongoing atrial fibrillation, high blood pressure, and scoliosis. Concomitant medications included ongoing acetylsalicylic acid (ASPIRIN) for atrial fibrillation, naproxen, pregabalin, tramadol, and metoprolol. The patient never had a history of blood clots. There were no allergies to report. The patient had not received any other vaccines in the four weeks prior to receiving BNT162b2. The patient had received the first single dose of BNT162b2 on an unspecified date, in the left arm. The patient's daughter stated that her mother suffered a stroke due to a large blood clot to the brain on 25Mar2021 at 12:30 am, requiring hospitalization. During hospitalization, a surgery to remove blood clot from the brain was needed. Hospitalization lasted 12 days. The reporter added that in the week prior to the reporting, the mother 'passed' (as reported) but had widespread blood clots in both of her arms. The patient required unspecified treatment due to the events and had not recovered at the time of the reporting. The events were considered also serious since life threatening and due to disability. The patient did not have COVID-19 prior to the vaccination and had not tested positive post vaccination. Information on lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1279039-1	50-59 years	8 days	Large blood Clotting after each dose during menstrual cycle.Bled for more than 2 weeks.; Large blood Clotting after each dose during menstrual cycle.Bled for more than 2 weeks.; This is a spontaneous report from a contactable consumer (patient). A 51-year-old female patient (not pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), second dose via an unspecified route of administration, administered in Arm Right on 19Mar2021 04:15 (at 51 years old, not pregnant), single dose for covid-19 immunisation. Medical history included stroke, high blood pressure, diabetes mellitus, all from an unknown date and unknown if ongoing. The patient's concomitant medications was unspecified (mentioned other medications in two weeks: yes but prescribed). The patient had her first dose of BNT162B2 vaccine on 26Feb2021 04:15 at 51 years old, for COVID-19 immunisation on left arm. The patient experienced large blood Clotting after each dose during menstrual cycle. Bled for more than 2 weeks. All on 27Mar2021 12:00. No other vaccine in four weeks. No covid prior vaccination. Not covid tested post vaccination. No known allergies. No treatment for the events. The outcome of the events was unknown. Information about lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1288388-1	18-29 years	8 days	Developed two blood clots in my left calf; This is a spontaneous report from a contactable consumer, the patient. An 18-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot unknown, first dose) solution for injection intramuscular in the right arm on 05Apr2021 at 10:00 (at the age of 18-years-old) as a single dose for COVID-19 vaccination. Medical history included ADD (attention deficit hyperactivity disorder). Concomitant medication included mirtazapine (AVANZA). The patient had no known allergies. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient developed two blood clots in my left calf on 13Apr2021 at 14:00 which resulted in emergency room/department or urgent care visit. Treatment for the event blood clots included rivaroxaban (XARELTO). The outcome of the event blood clots was recovering. The patient was not tested for Covid post vaccination. Information on the lot/batch number has been requested.
COVID19 VACCINE	UNKNOWN MANUFACTURER	1211915-1	40-49 years	8 days	Pt had L side chest pain, ultimately diagnosed w/ pulmonary embolism, started on anticoagulation, referred for outpatient follow up
COVID19 VACCINE	JANSSEN	1112768-1	50-59 years	9 days	Patient developed an extensive acute, occlusive thrombus in the external iliac, common femoral, popliteal, and gastrocnemius veins
COVID19 VACCINE	JANSSEN	1133212-1	30-39 years	9 days	The patient was experiencing headaches 1 week ago. She also had aphasia later in the week. She went to an outside hospital on 3/24/2021 and was found to have intraparenchymal hemorrhage in addition to venous sinus thrombosis. She is being treated for the venous sinus thrombosis with heparin.
COVID19 VACCINE	JANSSEN	1201543-1	30-39 years	9 days	Death
COVID19 VACCINE	JANSSEN	1202402-1	65+ years	9 days	Swollen of left leg and foot, took her to Delnor Hospital ER and they ran test.

COVID19 VACCINE	JANSSEN	1203929-1	50-59 years	9 days	Developed DVT. Complains of calf pain and swelling starting evening of 4/8/2021, worsening over weekend. To walk in care on 4/13/2021. Dx DVT in left lower extremity. Ultrasound shows DVT in the proximal femoral vein through the portal vein. Physician notes indicate patient seen for ""left leg soreness, tender to touch, protruding veins, redness, cramping in calf, radiating up to posterior thigh""
COVID19 VACCINE	JANSSEN	1204249-1	60-64 years	9 days	Deep vein thrombosis, left leg
COVID19 VACCINE	JANSSEN	1209660-1	65+ years	9 days	Patient went to hospital with chest pain on 3/17 and was found to have a pulmonary embolus. Started on anticoagulant. Had full workup
COVID19 VACCINE	JANSSEN	1209797-1	65+ years	9 days	vomiting, shortness of breath, hospitalized, chart shows she suffered from blood clot, hospital has extensive records from tests
COVID19 VACCINE	JANSSEN	1213048-1	60-64 years	9 days	initial symptoms- rash, itching, elevated BP, headache, ankle swelling ultrasound on 4/6/2021 - bilateral DVT CBC low platelets - 16 thousand CT chest - moderate burden PE Pt. was hospitalized
COVID19 VACCINE	JANSSEN	1215016-1	60-64 years	9 days	I received the Janssen vaccine on March 13. By the next weekend, I had what I thought was a spider bite on the inside of my left thigh. That ""bite"" got worse-bigger, hot to the touch, and then red. On the weekend of the 27-28 of March, it was red, raised and very painful even when not touched. I called my family doctor on Monday morning, the 29th of March, and I was sent to the Emergency Room, where I was diagnosed with a 7cm thrombosis in my left greater saphenous vein, which is treated the same as a DVT. I was treated first with Lovenox injections, then Eliquis 10 mg 2x daily, now 5 mg 2x daily. The blood clot is still painful to the touch.""
COVID19 VACCINE	JANSSEN	1218398-1	65+ years	9 days	4/7/21 patient presents to ED with severe left arm pain and neck pain, dopplar shows occlusive thrombus in left cephalic vein 4/9/21 patient goes in to cardiac arrest; found to have an INR>10 and concern for life-threatening bleed that required treatment with KCentra; intubated and sedated; liver shock, heart failure with reduced ejections fraction; troponin elevation 4/13/21: patient extubated; patient's wife informs Dr. that patient was vaccinated on 3/31 with Jansen product after seeing news reports regarding adverse events 4/16/21 patient expected to be moved out of CCU to medical floor
COVID19 VACCINE	JANSSEN	1219468-1	40-49 years	9 days	? Acute CVA (cerebrovascular accident) Hospital Course/test results: Work up with MRI showed 2 small acute infarcts in R temporal lobe region, and findings which could represent subacute infarcts in L frontal lobe. Neuro deficits now resolved. Neurology consulting. Suspicious for embolic phenomenon. She does also have a IUD to treat her menorrhagia, which may predispose her to clotting. However when we did further research Mirena IUDs were not found to raise the risk for blood clot-related heart attack and strokes but the company does recommend clinical consideration for removal in such situations. We contacted OBGYN oncall physician and spoke to doctor today. From his recommendation is not to remove the IUD at present time because the risk is very low comparing to the higher risk of severe menorrhagia that patient had experienced in the past. Since she will have annual visit with her GYN at OBGYN, patient should have that conversation with her GYN for options. Patient remains stable and symptoms free. Repeated brain MRI and new MRV did not reveal new findings. Her HA resolved on its own. She was initially started statin and full dose of ASA then changed to low dose ASA plus Plavix (21 days) then ASA as monotherapy after. Currently hypercoag panel is still pending. Echo showed no evidence of intracardiac shunting with fair quality and technically adequate study. Neurology recommended outpatient follow up with neurologist and 30 days heart monitor to look for Afib/flutter. Currently her headache is resolved as well R hand weakness/tingling is resolved. She is stable to go home today. A1C is 7.3 while on Metformin (2000mg daily). She may need additional agent to get A1C < 7 as outpatient. Neuro also recommended outpatient sleep study.
COVID19 VACCINE	JANSSEN	1220068-1	30-39 years	9 days	Pt had right sided chest pain x3 days starting 4/12/21, had a week of cough, fever, ""general not feeling well"" prior to ER admission 4/15/21. Had CT scan in ER on 4/15/21 - per radiology report a clot and pneumonia noted in RUL of lung. WBC count >22, elevated D Dimer, T Max in ER was 102.2. Was given PO Tylenol, 100mg Lovenox Subq, and IV antibiotics and flown to hospital.""
COVID19 VACCINE	JANSSEN	1225905-1	30-39 years	9 days	ADVERSE EVENT: DEEP VEIN THROMBOSIS SYMPTOMS: RIGHT INNER THIGH PAIN TIME: 9 DAYS POST VACCINATION
COVID19 VACCINE	JANSSEN	1229236-1	65+ years	9 days	Per history, patient experienced a ground-level fall early 4/16, and was noted to have weakness on his left side. Patient was brought to the ER 4/18 with concern for CVA, found to have acute pulmonary embolism.

COVID19 VACCINE	JANSEN	1233047-1	30-39 years	9 days	38 y/o F pt with a PMH of DVT, CVA, presents to the ED with complaints of left thigh and calf pain. Diagnosis of DVT in left leg.
COVID19 VACCINE	JANSEN	1237803-1	30-39 years	9 days	Presented to ED 4/18 with severe L sided chest pain since 4/17. Arm weakness and numbness 4/18 that lasted a few hours but resolved. No vision changes. O2 sat was 100% on room air. Diagnosed with PE. No recent mobilization. Does not smoke or use illicit drugs. Was admitted to the hospital telemetry unit 4/18-4/20. Discharged on apixaban. I do not have any information on the vaccine Lot number received.
COVID19 VACCINE	JANSEN	1239125-1	65+ years	9 days	Patient admitted with DVT, acute occlusive venous thrombosis in the left posterior tibial and peroneal veins.
COVID19 VACCINE	JANSEN	1239133-1	30-39 years	9 days	I received the vaccine on the 7th and in the night a migraine started along with fever on and off and on the 16th I went to the Emergency room with a migraine and chest pains and after running some tests I have pulmonary embolisms
COVID19 VACCINE	JANSEN	1246421-1	30-39 years	9 days	LEFT BRACHIAL VEIN DVT.
COVID19 VACCINE	JANSEN	1246686-1	50-59 years	9 days	Vomiting, vision impairment (read very slow to me), and seizure(s). Rushed to ER in ambulance. Was put on a ventilator (sedation). Received a CT scan showing a CVST and hemorrhaging in her right temporal lobe. Life-lined to Hospital. Wore an EEG on her head to monitor seizure activity for 4-5 days. Was put on 4 types of seizure medication and blood thinner for the clot. Did another CT scan which showed her Mid-Line shift was pushing into the left side of the brain by 15mm. Discharged from Hospital on 3/27/21 to Rehabilitation Hospital. She was discharged to home with a caregiver on 4/16/21. She will continue outpatient therapy at the rehabilitation hospital. She will see Speech, Vision, PT, and OT every week until further notice.
COVID19 VACCINE	JANSEN	1246863-1	60-64 years	9 days	Shortness of breath, blood clot in lungs
COVID19 VACCINE	JANSEN	1246877-1	65+ years	9 days	developed bilateral swelling and cough/subjective shortness of breath. Found to have bilateral DVT with likely several PEs (not confirmed). Patient started on SQ Lovenox.
COVID19 VACCINE	JANSEN	1247831-1	65+ years	9 days	80 yo male received J&J COVID-19 vaccination on 2/5/21. Pt with history of bladder cancer (s/p TURBT 11/04/2020), COPD (quit smoking 1 month ago) on 2 L nocturnal O2, HTN, CAD, MI s/p CABG x3v, apical cardiac aneurysm s/p repair, recent hematuria requiring cessation of chronic warfarin therapy who presented on 2/14 as a direct admission for evaluation of NSTEMI and new LLE DVT. He was initially placed on heparin and was stopped due to anemia and hematuria. DVT at outside hospital, repeat dopplers negative at our institution. Acute R femoral DVT likely due to patient being taken off chronic anticoagulation with warfarin. Discussed case with heme and not needed for IVC filter.....and even though cardiology would like him on long-term AC given high risk for LV thrombus, bleed risk outweigh benefit at this point. He was diagnosed with new HFrEF and NSTEMI. He will stay on hydralazine, imdur, lasix every other day, baby asa, and statin.
COVID19 VACCINE	JANSEN	1248053-1	40-49 years	9 days	Patient received J&J vaccine on April 9th. She stated to experience a left sided headache on 4/14/21. She was hospitalized late on 4/17/21 and was diagnosed with a pulmonary embolism on 4/18/21.
COVID19 VACCINE	JANSEN	1257669-1	40-49 years	9 days	Pt had vaccine on April 6, 2021 and was in the ER on April 15, 2021 with a right popliteal blood clot
COVID19 VACCINE	JANSEN	1260970-1	65+ years	9 days	Right arm sharp pains began within 1 week of receipt of the vaccine. Pain present with laying on the arm. Right arm pain persisted with swelling presenting on 4-26-21.
COVID19 VACCINE	JANSEN	1262581-1	50-59 years	9 days	Developed superficial leg clot on leg leg from ankle to grion
COVID19 VACCINE	JANSEN	1268087-1	60-64 years	9 days	He received the vaccine, had very painful going in and tingling going down his left arm and to the elbow which was numb, and the left little finger was numb, and a dizzy spell afterward which was typical for him. He then on the 9th day had extreme intercostal pain in the ribs on the right side and his right shoulder extremely painful, low grade fever, chills, fatigue and inability to draw a full breath. He called the doctor and they were on the way to the clinic they told him to go to the ER based on his symptoms. He went to the ER and they admitted him and did blood work, and then did a chest x-ray, then a chest CT scan and it was positive for pulmonary embolism. He was treated with an anti-inflammatory through the IV and a blood thinner to the stomach. He was hospitalized for 1 full day, and discharged home with Eliquis double dose for 14 days and then a single dose until further notice. He is still having fatigue and aches on the right side of his brain and aches in his feet, but is to see a pulmonologist for his lungs, as it will take up to 6 months for it to resolve. He also has damage to the right side of the heart and lung. Is waiting to get a CT of the brain.

COVID19 VACCINE	JANSEN	1270243-1	60-64 years	9 days	Pt presents to ER with a 5 day history of left lower extremity swelling without significant pain.
COVID19 VACCINE	JANSEN	1289578-1	65+ years	9 days	Presented to ER with weakness and tired last couple of days. Left side of neck pain and headache, shortness of breath.
COVID19 VACCINE	MODERNA	0922669-1	40-49 years	9 days	Patient (myself) developed DVT/PE diagnosed on 1/4/2021
COVID19 VACCINE	MODERNA	1068814-1	65+ years	9 days	9 days after vaccination, the patient was found deceased in his home, sitting on his couch. Determined to be due to pulmonary embolism.
COVID19 VACCINE	MODERNA	1069009-1	65+ years	9 days	Several days after vaccination his left arm turned red. He was taken to the hospital where he was evaluated and admitted with a diagnosis of left axillary vein thrombosis. A chest X-ray was taken and he presented bibasilar atelectasis and pneumonia with pleural effusions.
COVID19 VACCINE	MODERNA	1074118-1	50-59 years	9 days	Renal artery blood clot causing renal infarction
COVID19 VACCINE	MODERNA	1110391-1	60-64 years	9 days	Received vaccine, and no reactions. Nine days after the vaccine slowly had drooping on the right side of his face, numbness on the right side of his face, mainly around the mouth, a little on the eye, hard to close the right eye. General soreness around his mouth when he tries to eat or talk a lot. Limited movement of his face do to swelling, difficulty closing his eye, and headache. Went to the ER on 3/7/21 and admitted him as they believed he had a blood clot, diagnosed him with Bell's palsy on Monday 3/8/21. Was given corticosteroids for 9 days Prednisone 60 mg. The symptoms are slowly improving but still has the Bell's palsy.
COVID19 VACCINE	MODERNA	1153405-1	65+ years	9 days	MODERNA COVID-19 Vaccine EUA Patient received first dose of Moderna COVID vaccine on 1/20/2021, presented to Emergency Department on 1/29/2021 with complaints of left-sided chest pain below her breast, with an onset 1/26/2021. In ED diagnosed with Pulmonary Emboli in lower branches of left lung, and a urinary tract infection. Pulmonary Embolism diagnosed with CTA of Chest. Patient treated with Apixiban 10 mg BID with anticipated duration of therapy for at least 6 months. Patient subsequently received second dose of Moderna COVID vaccine on 2/26/2021
COVID19 VACCINE	MODERNA	1177623-1	40-49 years	9 days	Woke up on 4/4 with a golf ball sized, raised welt at the injection site. It was hot and very red. The next day, it was even larger, by 4/7, it had completely gone away. Everyone thinks I should also mention that I was admitted to the hospital with chest pain, high BP/Pulse on 3/31, they did a D-Dimer on me and it was elevated, suggesting a clot has formed and is in the process of breaking down. I had a CT of my chest and no PE was found, but I had thickening of my left lobar pulmonary artery wall, further supporting the suggestion of a possible blood clot. After an echo stress test, I was discharged the next day on HTN meds. I was experiencing chest discomfort prior to my vaccine, but again, EVERYONE is telling me I need to report this, so I am. :)
COVID19 VACCINE	MODERNA	1210520-1	60-64 years	9 days	Cranial and spinal SAH hematoma at roughly same time as heart attack. Cause of hematoma was unknown. Potentially a side effect of elliquis; but her cardiologist does not believe ellipsis was the cause. Heart attack at similar time due to blood clot and blocked artery and possibly reaction of body to hematoma. We do not have any hard data that either are related to the vaccine; but are reporting them under the advice of a doctor to give information for science.
COVID19 VACCINE	MODERNA	1213492-1	60-64 years	9 days	on Saturday, March 27th, patient noticed swelling in left lower leg with Shortness of breath, and heart racing. on 3/39, the patient presented to the ED and was admitted and diagnosed with a blood clot from left groin to left ankle, with ""clot in heart and lungs"". heparinized and discharged home on Coumadin currently taking 5 mg on Sunday, Monday, Wednesday, and Saturday and 2.5 mg on Tuesday and Friday each week.""
COVID19 VACCINE	MODERNA	1267593-1	65+ years	9 days	Headache, Increasing fatigue and difficulty breathing over two weeks before 2nd dose – exacerbated by 2nd dose. Worsening condition led to visit to Primary Care In office tests indicated presence of blood clots and need for emergency hospital treatment. Emergency surgery to remove blood clots throughout her body and attempt to put her on ECMO were unsuccessful and patient succumbed at 12:06 AM 3/3/21.
COVID19 VACCINE	PFIZER\BIONTECH	0936435-1	30-39 years	9 days	Had a blood draw in left arm 12/24/2020. Eventually led to superficial venous thrombosis of left basilic vein confirmed by duplex us and ct angiogram w/ contrast. Indentured vein led to seek diagnosis and treatment
COVID19 VACCINE	PFIZER\BIONTECH	0981787-1	60-64 years	9 days	pulmonary embolism that presented with chest pain and inability to take a deep breath, admitted and started on Heparin drip. Patient transitioned to Apixiban.

COVID19 VACCINE	PFIZER\BIONTECH	0992603-1	65+ years	9 days	Had vaccine on 1/18. No reported fevers or change in functional status/fatigue. Patient appeared in usual state of health. Is ambulatory with rollator. No prior h/o DVT. Was found in bathroom after presumed fall on 1/27. When attempted to lift patient become hypotensive (40-60 systolic). hypoxic (PO would not read). Was placed on 10 L oxygen without PO reading. Sent to ED-required 15 L nonbreather to get PO into 90s. Was diagnosed with large bilateral PEs. Found to have dvt RLE. Patient was hospitalized 4 days. His covid test was negative. He returned to facility without oxygen, on Eliquis.
COVID19 VACCINE	PFIZER\BIONTECH	1020333-1	65+ years	9 days	Had swelling in leg for a couple of days prior to the early morning of 1/31 where the knee and entire lower leg was swollen and painful and made it very painful to walk. After sending photo to primary care physician had mom evaluated for a blood clot. It was determined based on blood test, vascular ultrasound that right non occlusive (mid) Femoral vein DVT.
COVID19 VACCINE	PFIZER\BIONTECH	1029180-1	65+ years	9 days	Bilateral lung emboli Acute cor pulmonary
COVID19 VACCINE	PFIZER\BIONTECH	1044071-1	30-39 years	9 days	I had a major stroke on 12/25/2020, 9 days after receiving the vaccine. I had a clot in my MCA. My left arm was completely flaccid, with left facial droop and garbled speech. Thankfully I was able to receive TPA that day, which resolved all of my symptoms.
COVID19 VACCINE	PFIZER\BIONTECH	1049150-1	65+ years	9 days	Feb 9, patient was light-headed, as if he was going to faint. He did not have appetite. Evening of Feb 9, started vomiting large amounts of blood. Ambulance took him to hospital. CT scans showed abnormally enlarged pancreas. Patient aspirated blood and was put on a ventilator for 48 hrs. Endoscopic ultrasound showed ulcers in stomach that appear to have been bleeding, which were clipped and shot with epinephrine. After being treated for ulcers, patient developed blood clots in leg and lungs. It is almost two weeks since initial emergency, and patient is still showing signs of internal bleeding (low blood pressure, low hemoglobin, blood in stool). Still no firm explanation for continued bleeding. Before adverse event on Feb 9, patient did not report other symptoms from shot, however, he did show unusual signs of large bruising on his arm. Patient is currently at Hospital. Blood thinners are being discontinued, but patient still has blood clots.
COVID19 VACCINE	PFIZER\BIONTECH	1095124-1	65+ years	9 days	Chest pain DOE (dyspnea on exertion) Pneumonia of both lungs due to infectious organism, unspecified part of lung Acute pulmonary embolism, unspecified pulmonary embolism type, unspecified whether acute cor pulmonale present Death
COVID19 VACCINE	PFIZER\BIONTECH	1095904-1	65+ years	9 days	Sometime in the week following the administration of the vaccine I developed two unprovoked DVTs and one SVT in my left leg and one unprovoked SVT in my right leg.
COVID19 VACCINE	PFIZER\BIONTECH	1109729-1	60-64 years	9 days	03/07/21: Onset of dyspnea upon exertion 03/09/21: Worsening dyspnea and non-productive cough 03/11/21: Primary care visit for diagnosis/tests 03/12/21: Elevated BNP levels noted; chest X-ray 03/13/21: Further worsening of dyspnea 03/15/21: D Dimer test elevated (positive) 03/15/21: ED visit; CTA scan indicates pulmonary emboli (lots of clots); admitted to hospital; Heparin IV drip 03/16/21: (evening) Discharge on Eliquis 03/17/21: Moderately severe dyspnea upon exertion and non-productive cough continues Event: Pulmonary emboli
COVID19 VACCINE	PFIZER\BIONTECH	1118914-1	65+ years	9 days	SHORTNESS OF BREATH PT bibm c/o sob, per medics new afib rvr with elevated respirations and low etO2 and bp. patient had a recent covid vaccine last week. Chest x-ray is normal but her BNP is elevated which may be related to her underlying ischemia

COVID19 VACCINE	PFIZER\BIONTECH	1150956-1	65+ years	9 days	<p>Patient has substantial bilateral lung PE 12 days post vaccination; This is a spontaneous report from a contactable other health professional. A 65-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration on 05Mar2021 (at the age of 65 years) as single dose for covid-19 immunisation. Medical history included allergies: penicillin and testim. The patient's concomitant medications were not reported. The patient previously took the first dose of bnt162b2 on an unspecified date for covid-19 immunization. The patient had substantial bilateral lung PE (pulmonary embolism) 12 days post vaccination on 14Mar2021 (as reported, pending clarification). The event resulted in emergency room/department or urgent care and hospitalization in Mar2021. Treatment of heparin infusion with rivaroxaban (XARELTO) initiation planned was received for the event. The patient had no covid prior vaccination and had not tested post vaccination. Outcome of event was recovering. Information on the lot/batch number has been requested.; Sender's Comments: Based on temporal association, the contribution of the suspect drug to the onset of event pulmonary embolism cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1151636-1	65+ years	9 days	<p>My father received his first Pfizer vaccine on 02/03/21. On 2/12/21 I rushed him to the ER. He was vomiting uncontrollably and had shortness of breath. Once arrived at ER, they immediately put him on oxygen. Vomiting lasted several hours. They tested him for Covid and did a chest x-ray. Tested positive for Covid. Chest x-ray showed Covid pneumonia. Was admitted. Stayed in hospital for 5 days and was then released to nursing home for physical and occupational therapy. He was very weak and on days experienced what they called Covid fog. After 2 weeks of therapy, he was released on 03/06/21 to go back home to his apartment, with extended visiting nurse therapy. On 3/10/21, was the first visiting nurse appointment. At 12:00 an RN came to his apartment from Home Health Care. She checked his vitals. She said his blood pressure was good, lungs sounded good and oxygen level was 98. She said he was doing good and that she would not need to continue to come out and check on him weekly. She left. At 2:30 the same day, a Physical Therapist from Home Health Care came. She asked him lots of questions and adjusted my fathers' walker for him. He showed her how he was doing using the walker. Walked approximately 15-20 feet in his apartment. She checked his vitals before she left. His oxygen level was now at 91. She had him take a few deep breathes until his oxygen level was up to 93. She left and said she would be back on Friday the 12th to begin the actual physical therapy then. Within 10 minutes after she left my father started shaking uncontrollably and was having difficulties breathing. I called 911. Paramedics arrived. My fathers' oxygen level was all the way down to 74. They took him to the ER. When getting him out of ambulance he began vomiting. Vomiting lasted for hours just like when he went to the hospital back in February. They tried 3 different drugs to control the nausea. They did EKG, chest and abdomen scans. Was found that he had multiple blood clots and inflammation in his lungs and a bacterial infection in his blood. After testing, bacteria was found to be E Coli. Treated him with heparin for clots and antibiotics for infection and had him on oxygen in nose. Every day thereafter, he felt worse. They switched him to a high flow oxygen mask to keep his oxygen levels up. By Saturday night (early morning Sunday) on 03/14, they had taken the high flow oxygen mask off and hooked him up to a BiPap oxygen machine because his oxygen levels were dropping too low. We were then told by the lung doctor, that the damage to his lungs was extreme and that the next step would be to put him on a ventilator and feeding tube. My father did not want this per his will and his discussion with Dr earlier in the week. Dr indicated that he would not get better just being on the BiPap machine and we then chose to have them take him off of the machine because he did not want to go on life support. My father passed away on Sunday, March 14th around 6:30pm.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1153487-1	65+ years	9 days	Blood clots; This is a spontaneous report from a contactable consumer (reported for herself). A 65-years-old (non-pregnant) female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Solution for injection, Lot Number: EN6199, expiry date not reported), via an unspecified route of administration, administered in left arm on 03Mar2021 10:45 at a single dose for covid-19 immunisation. Medical history included atorvastatin (LIPITOR) and lisinopril, both taken for an unspecified indication, start and stop date were not reported. The patient had no other vaccine in four weeks. The patient had the vaccination on a public health clinic/veterans administration facility. On 12Mar2021, patient experienced blood clots that resulted in doctor other healthcare professional office/clinic visit, and emergency room/department or urgent care. The patient was not tested for Covid post vaccination. Therapeutic measures were taken as result of the event which included that the patient was put on blood thinners. The event blood clots recovered with lasting effects.
COVID19 VACCINE	PFIZER\BIONTECH	1160713-1	65+ years	9 days	DETAILS OF HOSPITAL STAY: PRESENTING PROBLEM: Cardiac arrest (HCC) [I46.9] HOSPITAL COURSE: Patient is a 74 year old female who receives care through healthcare clinic and second healthcare clinic with past medical history of HTN, CKD, cardiomyopathy/congestive heart failure, atrial fibrillation on Pradaxa who presented to the ED 3/16 after suffering an out of hospital cardiac arrest at her dentist's office. Per report, patient had SBP in the 80s on arrival but was asymptomatic. Prior to start of any procedure (no reports of being given sedative medications), she became unresponsive. CPR was initiated and was found to be in asystole. She received 3 rounds of CPR with ROSC. CT head without acute abnormality. Chest XR showing mild vascular congestion and interstitial edema. Initial labs showing AKI, elevated liver enzymes, BNP >29,000, troponin 39, lactic acid of 11, INR of 6.6, PTT 62, APTT 87. UA with protein, nitrite, moderate blood. Urine culture ordered. Blood cultures ordered. In ED, patient was hypotensive requiring addition of vasopressors. Targeted temperature management was started. Ceftriaxone and flagyl started for possible urinary tract infection and aspiration. Patient with profound coagulopathy, INR increasing to 12.0 on arrival to the ICU. Two units FFP and vitamin K were given. Patient with escalating pressor requirements at this time so CT t/a/p was ordered showing multiple bilateral rib fractures, nondisplaced sternal fracture with small anterior mediastinal retrosternal hematoma, small right sided hemothorax, right chest wall hematoma, patchy bilateral airspace disease consistent with atelectasis/infiltrate/aspiration, diffuse GGO consistent with interstitial edema, enlarged pulmonary arteries consistent with pulmonary hypertension, cholelithiasis. FDP elevated and 2 units of cryoprecipitate given 3/16. Hemoglobin decreased to 5.9 3/17 with INR of 5.4. Two additional units of FFP and additional dose of vitamin K ordered. Two units RBCs ordered. CTA thorax and abdomen 3/17 re-confirmed hemothorax and chest wall hematoma but no active bleeding noted. CT bilateral LE showed no evidence of hematoma. Trauma consulted who recommended chest tube placement. Overnight 3/16-3/17, patient also noted to have seizure activity on EEG and patient loaded with Keppra. Head CT 3/17 negative for hemorrhage or other acute processes. Patient remained in status epilepticus 3/17am and additional Keppra load was given and neurology consulted. Received Praxbind for continued bleeding/coagulopathy. 3/17pm went into PEA arrest with 10 minutes of CPR with ROSC. Bronchoscopy following ROSC noted evidence of bleeding from multiple areas, clots removed. MRI brain showing diffuse anoxic brain injury. Propofol stopped 3/19am. After goals of care discussion this morning, all first degree relatives (daughter and son) all in agreement to transition to comfort care measures. I received call from bedside RN that patient had passed away. On exam, no heart or breath sounds appreciated upon auscultation for 2 minutes. No spontaneous movement or chest rise noted. No pulse palpated for two minutes. Pupils fixed and dilated. No response to noxious stimuli. Time of death 1400 3/20/2021.

COVID19 VACCINE	PFIZER\BIONTECH	1162114-1	50-59 years	9 days	DVT Lower Right Leg; This is a spontaneous report from a non-contactable consumer (patient). A 58-year-old male patient received the first dose of bnt162b2 (BNT162B2 reported as PFIZER COVID-19 VACCINE), via an unspecified route of administration in the left arm on 04Mar2021 16:15 (lot number: EN6199) as a single dose for covid-19 immunization. The patient's medical history concomitant medications were not reported. The patient was not diagnosed with covid prior vaccination. On 13Mar2021, the patient had DVT lower right leg which resulted in doctor or other healthcare professional office/clinic visit. The patient received treatment for the adverse event which included Warfarin/Enoxaparin. The patient has not been covid tested post vaccination. The outcome of the event was not recovered. No follow up attempts are possible. No further information is expected.
COVID19 VACCINE	PFIZER\BIONTECH	1178277-1	65+ years	9 days	Deep vein thrombosis in the left calf; This is a spontaneous report received from a contactable consumer (patient). A 73-year-old male patient received the second single dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration, in left arm, on 06Feb2021 (Lot Number: EM9810), at the age of 73 years old, for COVID-19 immunisation. The patient had previously received the first single dose of BNT162b2 in the left arm on 16Jan2021 (lot number: EL8482). The patient had not received any other vaccines within 4 weeks prior to the BNT162b2 administration. Prior to vaccination, the patient had never been diagnosed with COVID-19. The patient's medical history included essential thrombocythaemia and benign prostatic hyperplasia. There were no allergies to report. Concomitant medications included hydroxyurea, simvastatin, mirtazapine, and acetylsalicylic acid (ASPIRIN). The patient stated developing deep vein thrombosis in the left calf on 15Feb2021, at 06:00 (10 days after 2nd shot), requiring a visit to ER. The patient was treated with enoxaparin (LOVENOX), followed by dabigatran etexilate (PRADAXA). Since the vaccination, the patient not been tested for COVID-19. The patient was recovering from the event. Follow-up Information has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1183385-1	60-64 years	9 days	leg DVT 8-9 later followed by PEs 4 days after DVT
COVID19 VACCINE	PFIZER\BIONTECH	1187953-1	50-59 years	9 days	INTENSE PAIN IN THE HAND OF THE LEFT ARM, IMMOBILITY OF THE HAND AND FINGERS. EMERGENCY ADMISSION
COVID19 VACCINE	PFIZER\BIONTECH	1207498-1	40-49 years	9 days	blood clots in the both lungs
COVID19 VACCINE	PFIZER\BIONTECH	1208308-1	60-64 years	9 days	Extreme pain in lower R leg, which had had a femoral bypass in May 2020. After a couple days I called my vascular team and they took me into surgery immediately. They did some kind of pharm treatment to break up the clot. Had procedure everyday for 3 days where they ultimately used some balloon device to open up the artery again. Still monitoring, am scheduled for another follow-up next week. I'm still vertical, but they had said the leg itself might be in jeopardy. Not happy with Pfizer, that's for sure.
COVID19 VACCINE	PFIZER\BIONTECH	1209115-1	30-39 years	9 days	On April 6 a.m. developed fever-like symptoms with muscle pain typical foe fever with these symptoms steadily worsening by evening. Night shower at appr. 9 p.m. caused a feeling of spinal nerve pinch followed by acute pain during certain movements and breathing. Following day (Wednesday) spent in bed taking Ibuprophene thinking is just a nerve pinch. Called virtual appointment tele doctor who prescribed Katorolac which I took from Wednesday night to Thursday morning per prescription with no effects. On Thursday evening called tele doctor again and got Ibuprophene 800 mg prescription. It helped for 20-30 min only. Same evening coughed some blood. On Friday kept taking Ibuprophene for very temporary relieve. On Saturday April 10 was admitted to hospital and was hospitalized with blood cloth diagnosis for 4 days.
COVID19 VACCINE	PFIZER\BIONTECH	1209247-1	18-29 years	9 days	Severe Vascular Thrombosis (vomit, loss of balance, numbness in arms and legs, lost of speech, impaired vision) had to be hospitalized for 4 days, and had some brain damage from the thrombosis.
COVID19 VACCINE	PFIZER\BIONTECH	1212661-1	40-49 years	9 days	DVT in calf that turned in to substantial pulmonary embolisms in both lungs with no prior blood clot history. Treatment included a TPA to dissolve clots as well as vascular surgery to remove clots not dissolved in the left lung.
COVID19 VACCINE	PFIZER\BIONTECH	1214566-1	40-49 years	9 days	pulmonary embolism

COVID19 VACCINE	PFIZER\BIONTECH	1218252-1	18-29 years	9 days	29 year old- year old female with known protein S deficiency with strong family history without prior VTE, presenting after diagnosis of unprovoked RLE DVT and RLL subsegmental PE. She had no known injury, immobility prior to this event, in fact was exercising 6 days/week and working fulltime as an RN. Received the first dose of Pfizer vaccine on 12/23/2020, pain in RLE started 12/26/2020 . Diagnosed with RLE DVT and RLL subsegmental PE. Started Eliquis starter pack. She had some shortness of breath so she was switched back to Lovenox for 5 days. Then placed back on Eliquis. Reports heavy bleeding with period, near syncopal episode. Subsequently, had a syncopal episode and 2/5/2021- MRI brain pituitary- Subcentimeter rounded well-circumscribed T1 hyperintense and hypoenhancing lesion in the pituitary gland measuring 8 x 7 mm with questionable small volume blood layering at its base, may reflect either a hemorrhagic pituitary microadenoma or possibly hemorrhagic Rathke's cleft. Patient's labs were significant for a cortisol of 3 for which she was given hydrocortisone 100mg, as well as a 100mg IV hydrocortisone pre-operatively. Patient underwent a transsphenoidal resection for mass with ENT assistance on 2/8. She is on hydrocortisone 30 mg daily and Eliquis. Seen last on 2/24/2021- protein S - 36,
COVID19 VACCINE	PFIZER\BIONTECH	1219386-1	65+ years	9 days	On 02/26/2021, 10 days after given the vaccine I was admitted to the hospital with a blood clot in my left leg and in both lungs. I was given Heparin, admitted, started on Xarelto, released on 02/28/2021. I will be on blood thinners for a at least 90 days.
COVID19 VACCINE	PFIZER\BIONTECH	1220095-1	60-64 years	9 days	Felt sick with covid like symptoms beginning 4/2, Shortness of breath began 4/3, received negative covid test on 4/7, went to ER on 4/12, CT scan showed MASSIVE bilateral Pulmonary embolism, Angiogram of heart showed right side under stress at 50%. 4/13 Surgery - catheterized directed thrombosis to dissolve clots. Discharged from hospital 4/15
COVID19 VACCINE	PFIZER\BIONTECH	1225942-1	6-17 years	9 days	Patient was a 16yr female who received Pfizer vaccine 3/19/21 at vaccine clinic and presented with ongoing CPR to the ED 3/28/21 after cardiac arrest at home. Patient placed on ECMO and imaging revealed bilateral large pulmonary embolism as likely etiology of arrest. Risk factors included oral contraceptive use. Labs have since confirmed absence of Factor V leiden or prothrombin gene mutation. Patient declared dead by neurologic criteria 3/30/21.
COVID19 VACCINE	PFIZER\BIONTECH	1265981-1	40-49 years	9 days	This is a spontaneous report from a contactable pharmacist (patient's husband). A 46-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration, administered in left arm on 01Apr2021 (lot number: ER8733) at the age of 46 years old, as single dose for COVID-19 immunization. The patient's medical history was not reported. Concomitant medication included desogestrel, ethinylestradiol (ISIBLOOM) taken for birth control from an unspecified start date and ongoing. On Saturday, 10Apr2021, she was fine, but she had some pain on the left side of her body. On Sunday (11Apr2021), the pain was much ""much"" worse, and her breathing was affected. On Monday (12Apr2021), she had the same symptoms and was taken to the Emergency Department for her problems breathing. On 13Apr2021, she had blood clots, 2 of them in both lungs. She is on pain medication and it is improving for her. The only medication she is taking is birth control pills. She has been taking them for years with no complications. The reporter added not long ago, she was in the doctor for a physical and all was fine. The patient was hospitalized due to the events and was still admitted. The events resulted in emergency room visit. The patient was recovering from the events. Event assessment by the reporter for the events blood clot in both lungs, problem breathing and left side pain was reported as related to the Pfizer COVID-19 vaccine. Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.""

COVID19 VACCINE	PFIZER\BIONTECH	1269768-1	18-29 years	9 days	unprovoked right leg DVT; bilateral PEs; Factor V Leiden positive (heterozygous); right leg swelling and pain progressively worsening; right leg swelling; This is a spontaneous report from a contactable consumer (patient). A 29 year old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 19Jan2021 10:00 (Lot Number: EL1283) as SINGLE DOSE for COVID-19 immunisation. The patient previously had first dose of BNT162B2 on 29Dec2020 at the age of 29 years old for COVID-19 immunisation. Medical history included pleural effusion w/ thoracentesis x2 (5 years ago), known allergies: penicillin and sulfa drugs from an unknown date and unknown if ongoing. Concomitant medication included armodafinil taken for an unspecified indication, start and stop date were not reported. The facility where the most recent COVID-19 vaccine was administered was in the workplace. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19 (nasal swab): negative on 28Jan2021. On 28Jan2021, the patient presented to the ED with right leg swelling and pain progressively worsening over the past week. Subsequently diagnosed with unprovoked right leg DVT and bilateral PEs, admitted overnight and given anticoagulation therapy. Labs ordered and reviewed with hematology consult 1 week later and found to be Factor V Leiden positive (heterozygous). Treatment plan therapeutic dose of Eliquis twice a day for 1 year, prophylactic dose indefinitely after that. The events resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care and hospitalization. The events were reported as life threatening illness as patient was in immediate risk of death from the events. The patient was hospitalized for 1 day. The events was recovering. The events was treated with anticoagulation therapy, pain medicine and stockings.
COVID19 VACCINE	UNKNOWN MANUFACTURER	1230378-1	30-39 years	9 days	Pulmonary Embolism
COVID19 VACCINE	JANSSEN	1141160-1	50-59 years	10-14 days	Patient had 5 days of bruising and left leg swelling prior to presenting to the emergency department 3/26/21, where she was found to have an extensive occlusive DVT of left lower extremity as well as thrombocytopenia of 15,000. That evening she was taken to the Cath Lab and had an IVC filter placed. The next day patient began to have paresthesias and discoloration of the right lower extremity. Ultrasound showed high-grade occlusion of the right proximal superficial femoral artery. Patient was pre-treated with platelets and taken back to Cath Lab emergently. In addition to the right SFA there is also thrombotic occlusion of bilateral iliacs. Patient had bilateral thrombectomy and bilateral common iliac stent placement. The following day developed gross hematuria.
COVID19 VACCINE	JANSSEN	1146214-1	18-29 years	10-14 days	Was 5 weeks pregnant at time of vaccine with strong HCG levels, approximately 2 weeks after vaccination patient suffered a miscarriage. Vaginal bleeding, cramping and passed large clots including a sac like tissue.
COVID19 VACCINE	JANSSEN	1178023-1	30-39 years	10-14 days	Admitted with ischemic stroke and multiple thrombi in extremities
COVID19 VACCINE	JANSSEN	1196712-1	50-59 years	10-14 days	Couple days after they release patient from the hospital she start with Pain, we take her to the emergency room and they made a CAT scan finding a Blood Clot on the Porta vein, she start with Blood thinners and she still on treatment because that.
COVID19 VACCINE	JANSSEN	1200861-1	60-64 years	10-14 days	He had his vaccine in different state while visiting his daughter. Returned home and was found to have a blood clot behind his left knee. Also, he called the doctor last week and told him that he believes he has another one above the left ankle. He has an appointment on Thursday to see him again. He had two venous ablation procedure in both legs in late November/December of 2020. He was taken off of the baby aspirin and then put on Xarelto. The 2nd possible blood clot appeared about 10 days ago above the left ankle.
COVID19 VACCINE	JANSSEN	1201057-1	30-39 years	10-14 days	1st night very out of breath. O2 at 93 on sensor at home. Felt better next day. 3/29/21 - went to ER for blood clot in left leg.
COVID19 VACCINE	JANSSEN	1201164-1	65+ years	10-14 days	The patient had saddle pulmonary embolism on 3/24/2021 requiring hospitalization and thrombolysis. Currently the patient is on anticoagulation with Xarelto and is doing well.

COVID19 VACCINE	JANSSEN	1201443-1	30-39 years	10-14 days	14 DAYS POST VACCINE EXPERIENCED LEFT CALF PAIN...SHARP PAIN. Applied warm compress and took tylenol. Pain persisted and increased. Visited Urgent Care center on Tuesday, 3/23 and was advised immediate ultrasound needed. Went to Radiology Facility same day and was advised I had a DVT in leg and I needed to go to ER. Went to Hospital ER on 3/23 and was treated in ER with blood thinners (IV) and advised I also had numerous PEs in chest. Released with RX for Eliquis and advised to follow up with PCP and Hematologist asap. Friday, 3/26 leg was swelling and patient was dizzy with chest and arm sensations. Went back to ER. Double Doppler done. DVT has moved. Assumed another PE has occurred. Continue Eliquis RX. Following up with Hematologist, Cardiologist and Pulmonologist.
COVID19 VACCINE	JANSSEN	1201961-1	30-39 years	10-14 days	10 after I received the Janssen Covid-19 vaccine, I admitted myself to the emergency room with severe chest pain and very difficult time breathing. They ran CT scans and found multiple blood clots in both lungs, pulmonary embolism. They put me on blood thinners and transferred me to another hospital. There they monitored me for a couple days and released me with a prescription for blood thinners.
COVID19 VACCINE	JANSSEN	1202171-1	50-59 years	10-14 days	10 days after the vaccine I developed dizziness, tachycardia, dry mouth, chest pressure, shortness of breath and felt like I was going to pass out, and I had a feeling of extreme doom. I was transported to a clinic. There I had a heart rate of 140 with irregular beats. Continued feeling of doom. An EKG showed ST depression. Symptoms improved with nitroglycerin. The clinic didn't have the technology to provide care so I was emergently transported again. At that hospital my D-dimer was positive and that led to a CT Angiogram. This showed a pulmonary embolism. Doppler studies of both legs were negative. I was placed on Heparin for several hours and then switched to Eliquis. About 6 hours after being on Eliquis I had the exact same original symptoms and again nitro was given which helped the symptoms. I was placed back on Heparin for a longer period of time. Once I was anticoagulated I was then switched to Eliquis 10mg BID for 7 days then 5mg BID for 6-9 months. I had a CT Angiogram of the head and neck which was normal. At this time I still have dizziness with standing and intermittently with sitting, extreme fatigue, shortness of breath.
COVID19 VACCINE	JANSSEN	1202568-1	30-39 years	10-14 days	Possible blood clot in L knee, appears to be superficial. I get these frequently (about once a year).
COVID19 VACCINE	JANSSEN	1203390-1	50-59 years	10-14 days	Patient awoke with pain above and below knee on April 10, appointment with Provider on April 12, CBC and D-dimer along with US completed, patient diagnosed with Venous Thromboembolism.
COVID19 VACCINE	JANSSEN	1203985-1	65+ years	10-14 days	Pain, redness, swelling in right leg, below the knee, when I got up in the morning. Symptoms continued over the weekend. Called Dr. on Monday, April 5, 2021 and got an appointment for the following day. Dr. diagnosed it as phlebitis and sent me for an ultrasound. Prescribed Xarelto 15 mg twice a day for 21 days, then decrease to 20 mg daily.
COVID19 VACCINE	JANSSEN	1204058-1	65+ years	10-14 days	Patient started having abdominal pain on March 26, 14 days after vaccination. Went to ER on March 29 and was admitted. Diagnosed with blood clot in spleen. Discharged from hospital on March 31.
COVID19 VACCINE	JANSSEN	1204440-1	65+ years	10-14 days	Patient with mild shortness of breath for the past month. Travel a week ago. Received vaccine 03/29/21. Admitted on 04/11/21 for increased shortness of breath. CT angi showed extensive segmental pulmonary embolism. Patient doing well and discharged to home on 04/12/21 after being placed on Lovenox then transitioned to Eliquis.
COVID19 VACCINE	JANSSEN	1204702-1	65+ years	10-14 days	Patient seen in clinic on 04/07/21 reporting 2 weeks of right leg swelling and calf pain. Vascular ultrasound on 04/07/21 showed blood clots in legs. Lovenox injections started 04/07/21. Warfarin started 04/08/21.
COVID19 VACCINE	JANSSEN	1205766-1	50-59 years	10-14 days	I had rear end pain started March 20 in the morning, it gets worse and worse till 3/23 that I can not tolerate and had to call clinic to make appointment. They got me in on March 25 (Thursday). Dr inspected and told me it's thrombus that caused huge pain. They did the surgery right away, removed thrombus. I never had blood clots problem and I was healthy, which my blood test result can prove. Thrombus generated 12 days after my J&J vaccine shot, I am reporting this side effect. You may find all my medical record from Doctor's office.
COVID19 VACCINE	JANSSEN	1205934-1	30-39 years	10-14 days	Venous blood clot in leg, and lunnv
COVID19 VACCINE	JANSSEN	1206192-1	65+ years	10-14 days	DVT in right lower leg occurring within 2 weeks of vaccination
COVID19 VACCINE	JANSSEN	1206218-1	50-59 years	10-14 days	Left Distal Deep Vein Thrombosis Prescribed Eliquis for 3-6 mo.

COVID19 VACCINE	JANSSSEN	1207088-1	50-59 years	10-14 days	The week of April 5, I believe it was April 5 & 6, I thought that I was coming down with a sinus infection. I was having some blood when blowing my nose and remember seeing some small, hard balls which I now realize were clots. I did not go to the doctor because my back was very bad and I was in a lot of pain and I had an upcoming appointment with my doctor. I believe that the symptoms resolved after 2 or 3 days and I did not even mention it to my doctor when I saw him. I felt a lot of pain in my leg, but this is probably due to my ongoing sciatica/radiculopathy /bursitis problems that I experience.
COVID19 VACCINE	JANSSSEN	1207401-1	60-64 years	10-14 days	SUDDEN DEATH - PULMONARY EMBOLUS DUE TO DEEP VEIN THROMBOSIS RIGHT POPLITEAL VEIN
COVID19 VACCINE	JANSSSEN	1207817-1	30-39 years	10-14 days	3/17/21 - Pt tested positive for COVID-19 3/21/21 - Pt started to experience leg pain 3/23/21 - Pt went to hospital with DVT and multiple bilateral PE 3/26/21 - Pt returned to hospital due to leg swelling and tingling sensation in arm and chest Pt now is required to regularly follow up with hematology, pulmonology and cardiology.
COVID19 VACCINE	JANSSSEN	1208026-1	30-39 years	10-14 days	Patient received vaccine through pharmacy at employer vaccination event. Presented to clinic on 04/13/2021 and noted to have imaging confirmed ""There is occlusive superficial clot starting the upper lateral right thigh and extending distally through the mid to distal lateral calf. This appears to be within a superficial varicosity. Findings are consistent with extensive superficial thrombophlebitis of a varicose vein of the right lower extremity.""
COVID19 VACCINE	JANSSSEN	1208090-1	60-64 years	10-14 days	Left leg DVT April 11, 2021. Johnson and Johnson vaccine on March 12, 2021
COVID19 VACCINE	JANSSSEN	1208162-1	50-59 years	10-14 days	Blood Clot in right calf. deep arterial thrombosis
COVID19 VACCINE	JANSSSEN	1208315-1	50-59 years	10-14 days	Patients power of attorney called to let us know patient had received Janssen vaccine on 3/12/21 and on 3/26/21 was hospitalized due to a clot and stroke. Patient had history of strokes in past.
COVID19 VACCINE	JANSSSEN	1208568-1	30-39 years	10-14 days	Exact date and time of COVID vaccination unknown. Patient presented to Medical Center on 04/02/21 with left sided weakness and slurred speech. He reports receiving the COVID19 Janssen vaccine 15 days prior. Details of vaccination beyond patient report are unknown. Diagnosed with acute left cerebellar stroke, status post TPA on 04/02/2021. Extensive workup in hospital negative and unremarkable, including TEE, and hypercoagulable state so far negative. Follow up with hematologist as outpatient underway to evaluate for any possible coagulation disorders.
COVID19 VACCINE	JANSSSEN	1208600-1	50-59 years	10-14 days	Patient suffered from SOB 4 days after receiving injection, was diagnosed on 4/14/21 with bilateral PE's. Admitted to hospital.
COVID19 VACCINE	JANSSSEN	1208750-1	65+ years	10-14 days	Fell two weeks after immunization. Developed blood clot after procedure. Husband concerned immunization is cause of clot and not the surgery or down-time after the procedure. Transferred to new hospital from previous hospital and had significant stroke due to clot
COVID19 VACCINE	JANSSSEN	1209778-1	65+ years	10-14 days	Patient was admitted to the hospital 12 days (3/24/21) after vaccine dose administration (3/12/21) sent in for refractory abdominal pain, nausea and vomiting. On admission, a CT Abdomen/Pelvis with contrast was largely unremarkable including reported demonstration of patent portal vein. During the course of the hospitalization the patient developed a portal vein thrombosis visualized on 3/26 by ultrasound. She also received Heparin SQ from 3/27/21 through 4/2/21 but not sent home on anticoagulation. Her course was also complicated by a seizure and Bacteroides bacteremia. MR Brain did not demonstrate thrombosis
COVID19 VACCINE	JANSSSEN	1210766-1	60-64 years	10-14 days	3/29/21 6 pm - Severe pain lower right leg, ankle, and foot, unable to weight bear on right leg About an hour later I was able to walk a little. Stayed off my feet. Right foot became very cold. 3/30/21 Saw my primary care physician at med center. She sent me for an ultrasound at medical arts. From there I was sent to the emergency room at hospital. I asked the attending physician assistant about a correlation between the blood clot and the Covid vaccine because I had read about it being a concern in other countries. He stated that was a bunch of baloney. Was told to have a repeat ultrasound in a few days and was prescribed a 30 day starter pack of Xarelto and released. 3/30 repeat penis ultrasound of right leg showed the same results. 4/1 appointment with hematologist. Prescribe Xarelto for three months and ordered a repeat ultrasound in three months and bloodwork at that time.
COVID19 VACCINE	JANSSSEN	1210805-1	30-39 years	10-14 days	Deep vein thrombosis (DVT) of axillary vein of upper right extremity, sub clavain vein and pulmonary embolism of right and left lung. Treated with injected Lovenox.
COVID19 VACCINE	JANSSSEN	1210908-1	50-59 years	10-14 days	blood clot

COVID19 VACCINE	JANSEN	1212458-1	65+ years	10-14 days	2 weeks 8 days after vaccine, patient suffered which sent pt to emergency room. Husband states she had a ""blood clot"" to brain with skull fracture and traumatic brain injury. Transferred to Medical Center, then to long term facility. Has not recovered to date. Husband states unable to speak or move.""
COVID19 VACCINE	JANSEN	1212470-1	18-29 years	10-14 days	29yom with no significant medical history was diagnosed by CT with acute pulmonary embolism involving the branch vessel in the right lower lobe 14 days after receiving Johnson & Johnson vaccine. Symptoms of right pleuritic pain began 4 days prior to the diagnosis. Initiated therapy on oral anticoagulants.
COVID19 VACCINE	JANSEN	1212971-1	40-49 years	10-14 days	I had bloodwork showing increased D-Dimier and that I may have a blood clot.
COVID19 VACCINE	JANSEN	1213101-1	50-59 years	10-14 days	On 4/13/2021 at 11:00 AM pt. began experiencing left leg pain with swelling noted around left knee and extended above knee. By 11:00 PM pt. felt faint and nauseated and left leg was swollen and discolored. Rescue squad was called and took pt. to Hosp where she was told it was sciatica. After showing the medical professionals her leg and insisting upon an ultrasound of her leg she was told the ""machine"" was not available and she would be called the next day to be scheduled. Per pt's daughter, she was never called and daughter called hospital to have U/S scheduled. Pt. went back to hospital on 4/14 at 3:15 PM for U/S and she was diagnosed with multi DVT's in left leg which at that time had swelling all the way down to her foot. Pt. was put on Coumadin.""
COVID19 VACCINE	JANSEN	1213429-1	50-59 years	10-14 days	DIAGNOSIS: 1. Superficial thrombophlebitis MEDICAL DECISION MAKING/DIFFERENTIAL DX: Differential diagnosis includes DVT, superficial thrombophlebitis, muscle strain, tendinitis. The patient presented to the emergency department with atraumatic left leg pain. An ultrasound reveals a fairly large blood clot in the greater saphenous vein. Although this is a superficial clot, given its extent, I think it warrants anticoagulation. Per the trial, the patient would benefit from 45 days of 10 mg Xarelto treatment. The patient was given good precautions regarding bleeding risk while on a blood thinner. He will schedule follow-up appoint with his primary care doctor. He will also use Tylenol and warm packs to help with the discomfort from the superficial thrombophlebitis. He was discharged in satisfactory condition.
COVID19 VACCINE	JANSEN	1214423-1	50-59 years	10-14 days	Charlie horse began 10 days after vaccine, leg felt full with cramping not allowing motion, went to ER diagnosed with blood clot in left calf
COVID19 VACCINE	JANSEN	1214428-1	65+ years	10-14 days	Patient has blood clot
COVID19 VACCINE	JANSEN	1214815-1	40-49 years	10-14 days	Patient started not feeling well on 3/24. She was experiencing dizziness, headache, chills and fever. She contacted her doctor on 3/25 and he thought maybe she had an inner ear infection. Symptoms continued to worsen and eventually an ambulance was called on 3/27 because patient stated she was having severe SOB and headache along with dizziness and fever. Patient was transported to Hospital where they tested her for covid and pneumonia. Both came back negative. After several tests it was confirmed she had a blood clot in her lung and was also told she had clots in her leg and heart as well. She was in the hospital for 3 days where she was given heparin and several medications for the headache. Patient was discharged on lovenox and coumadin and eventually switched to xarelto by pcp who is managing her anticoagulation. She still has follow up appointments with a cardiologist and neurologist. She said she is still experiencing some dizziness and SOB but overall doing better
COVID19 VACCINE	JANSEN	1214907-1	60-64 years	10-14 days	Patient developed right lower extremity DVT (unprovoked) diagnosed on 3/26/21.
COVID19 VACCINE	JANSEN	1215019-1	65+ years	10-14 days	Patient right leg became very swollen from knee down and was very painful to walk. Patient went to Urgent Care and was told that he would need to have ultrasound done to see what was going on. Patient went to Imaging and was told that he had several blood clots through out his right leg. They advised him to go to emergency room evaluation. Patient went to Medical Center and it was confirmed that patient had blood clots and was put on Xarelto for treatment.
COVID19 VACCINE	JANSEN	1215397-1	18-29 years	10-14 days	4/1/2021 patient received JNJ Vaccine 4/12/2021 Miscarriage was confirmed on Ultrasound done by and also Right Pelvic vein thrombosis seen. 4/13/2021 Patient placed on Anticoagulation.

COVID19 VACCINE	JANSSEN	1215435-1	60-64 years	10-14 days	Patient began experiencing back pain on March 14 and on or around March 18 he started coughing up blood clots according to a coworker. Patient lived alone and was unable to be reached on Sunday March 21. I went over to his house and found him deceased in his bed. Patient had a trashcan beside his bed and it appeared to have some blood in it. Patient had thick mucus coming out of his mouth and blood coming out of his nose. According to paramedics he had passed a few hours before finding him. Unfortunately Patient has been cremated so there is no way to say that this was related to the Covid 19 shot from Johnson and Johnson, however there are new reports that blood clots have been a side effect. I would like to speak with someone from the Department of Health to discuss this further. I feel this could be related to the vaccination and I would to know how long the Health Department knew about this possible side effect. If patient would have known sooner that the blood clots were a side effect I feel he would have gone to the Emergency Room. Patient had no health insurance and he was trying to prevent getting Covid. This has caused our family so much heartache and we are all very apprehensive about getting the Covid Vaccine ourselves. Please contact me as soon as possible, I am also patient's executor so I am able to speak to you on behalf of patient and our family. Thank you.
COVID19 VACCINE	JANSSEN	1216452-1	65+ years	10-14 days	within 10 days I had severe breathing problems that lasted about 4 days, had test that revealed blood clots in my lungs about a week after
COVID19 VACCINE	JANSSEN	1217874-1	40-49 years	10-14 days	Per client self report: Experienced LLE extremity pain beginning on 4/11/2021, but thought nothing of it at the time. Client was previous scheduled for testing/procedure for asthma with pulmonologist on 4/15/2021, with pre-test/procedure lab work scheduled for Monday, 4/12/2021. Client presented for lab work on 4/12/2021 as scheduled and shortly thereafter received phone call from pulmonologist's office stating that the labs showed and elevated D-dimer and that she would be scheduled for a follow-up CT Scan of the chest and ultrasound of the lower extremities, which was scheduled on 4/14/2021. Client presented for CT scan of chest and ultrasound of lower extremities as directed and returned home on 4/14/2021. Client reported in conversation that she ""didn't feel right"" and noticed some SOB, and had planned to rest outside of going in for scheduled tests. Client received a phone call on 4/14 from pulmonologist's office advising her to go immediately to the emergency room due to a blood clot being found in the left lung as per CT scan report. Client presented to Emergency Room and was started on Eliquis 5mg tablets - 2 tablets by mouth twice daily X1 week and then 1 tablet by mouth twice daily and discharged to home. Client remains at home at the time of interview with no additional or worsening symptoms.""
COVID19 VACCINE	JANSSEN	1218886-1	65+ years	10-14 days	Bilateral arm swelling: 1. Occlusive thrombus is present within the right cephalic vein extending from the upper arm to the elbow. 2. Nonocclusive thrombus is present within the left basilic vein in the mid and distal arm. also developed acute appendicitis 04/06/2021 and underwent lap appendectomy.

COVID19 VACCINE	JANSSEN	1218973-1	30-39 years	10-14 days	Per hospital chart notes, known timeline of events is pieced together as follows: 2021-03-23 - patient received J&J COVID-19 vaccine at Drug Store 2021-03-24 - patient developed myalgias, headache, shortness of breath, and chills - resolved within 24 hours 2021-04-02 - patient developed headache intermittent from right to left side of head for which patient was seen at an urgent care. Patient was prescribed Fioricet (butalbital/acetaminophen/caffeine). 2021-04-05 - patient developed right-sided neck pain 2021-04-06 - patient got tested for COVID-19, resulted negative on 2021-04-07 2021-04-08 - patient seen at Medical Center emergency department for headache and right-sided neck pain that shoots to (2021-04-08 cont.) the head and shoulder, for which patient self-medicated with ibuprofen. Patient reported to ED provider that using ibuprofen nearly relieves headache and makes her functional and had the most improvement the day she visited the ED prior to her visit. Patient received a CT scan of the head without contrast that was unremarkable. Patient was diagnosed with headache and neck sprain and was prescribed ibuprofen 600 mg, take 1 tablet by mouth every 8 hours, and diazepam 5 mg, take 1 tablet by mouth 3 times a day as needed for muscle spasm. 2021-04-12 - patient developed left lower extremity pain 2021-04-14 - patient followed up with Neurologist outpatient as directed by ED provider and was advised to get an MRV and left lower extremity doppler. Patient was prescribed tramadol 50 mg and butalbital/acetaminophen/caffeine (Fioricet) by the Neurologist. 2021-04-15 - patient presented to Medical Center ED before outpatient MRV and LLE doppler could be done due to worsening right-sided neck pain and inability to ambulate comfortably due to lower extremity pain that had been worsening over several days. Upon examination, there is subtle swelling to left lower extremity and doppler revealed multiple DVTs in left lower extremity. CT head without contrast was unremarkable, however, CT venogram of the brain reveals thrombi of the right transverse sinus and sigmoid sinuses, as well as IJ. Patient was initiated on argatroban and admitted to inpatient at the time of this report. ""Heparin induced platelet antibody"" and ""lupus anticoagulant evaluation"" tests are ordered and pending.""
COVID19 VACCINE	JANSSEN	1219077-1	50-59 years	10-14 days	clotting in left leg
COVID19 VACCINE	JANSSEN	1219798-1	65+ years	10-14 days	Patient was in store and top of chest started hurting and down left arm. Patient states that they called 911 and ambulance took her to the hospital. She was tested and found to have mild heart attack with blood clot in vein of her heart. Had procedure to remove clot was put on blood thinner and is now wearing a heart monitor for the next 30 days. Is on Brelinta for the next 30 days as well. Patient went back to ER on Tuesday night (4/13/21) due to SOB spent 12 hours at ER before being transferred back to hospital. She spent another day and half before discharge diagnosed with fluid buildup.
COVID19 VACCINE	JANSSEN	1220359-1	65+ years	10-14 days	Patient admitted 4/14/2021 to the ICU from ED. Patient was experiencing hand weakness. Patient given TPA as treatment for a potential stroke. Patient with known stroke on CT imaging, unable to further verify with MRI imaging. Upon further investigation/discussion with the patient, he reports receiving the Johnson & Johnson Vaccine 10 days prior to admission. Patient with known comorbidities which increase his risk of an embolic stroke however with recent findings from the CDC, unsure if this needs to be further investigated. Patient had 2 head CT scans, showing no intracranial abnormalities and MRI was unable to be completed due to patient's size. Neurology states high probability of stroke within their consult note. Patient's risk factors for stroke include: uncontrolled hyperlipidemia (LDL 132 on Crestor 40 mg daily PTA), hypertension (as high as 182/92 mmHg in ED), physical inactivity (BMI 76 kg/m^2), and male. Low suspicion of CVST based on patient's platelet count of 212 on admission and no abnormality on head CT. MRI would have been beneficial in potentially diagnosing CVST, as well. Our recommendation is to submit this information to the VAERS database as a possible ADR from the vaccine. The patient fits the timing of an ADR, within 6-13 days of vaccine administration, and CDC recommends watching for neurological symptoms based on their most recent press release.
COVID19 VACCINE	JANSSEN	1221619-1	65+ years	10-14 days	Pain increased in left calf, clot found in left calf at medical center, rushed to different medical center, 6-1/2 hour surgery to remove clot in lower left leg. 100% blocked. Hospital diagnosis found left leg ischemia (199.8). Procedures performed, popliteal artery patch repair, Angiogram, fasciotomy calf.
COVID19 VACCINE	JANSSEN	1224712-1	30-39 years	10-14 days	DVST: R internal jugular, transverse/sigmoid sinus thrombus with associated intraparenchymal hemorrhage in R temporal lobe. Presented transfer from outside hospital after presented with 2 weeks headaches, blurry vision and 2-3 days neck stiffness and nausea with 1 episode of vomiting.
COVID19 VACCINE	JANSSEN	1226343-1	65+ years	10-14 days	pulmonary emboli- sob confirmed with CT scan

COVID19 VACCINE	JANSSEN	1227295-1	30-39 years	10-14 days	On April 16, 2021 (Day 13 after Vaccine) I was diagnosed with acute deep vein thrombosis (DVT) of my femoral vein in my left leg by Hospital. In other words, I was diagnosed with a blood clot in my upper left leg. Pain in both my legs had started on April 13, 2021 (Day 10 after Vaccine). On April 16, I had a virtual appointment with my doctor, Dr. , who prescribed an ultrasound to rule out DVT. I went to an ultrasound appointment at Radiology at 3:30pm where a blood clot was found in my left leg. I was admitted into the emergency room at Hospital and prescribed medication and follow ups from there. These adverse symptoms developed after I submitted other adverse symptoms to VAERS on April 13, 2021 (Temporary VAERS E-Report Number: 435841).
COVID19 VACCINE	JANSSEN	1227376-1	40-49 years	10-14 days	Shortness of breath, nausea, headache, incident of blurred vision in one eye. Had visit with PCP on March 26th with follow-up testing on March 30th and 31st. Condition worsened and went to emergency room on April 4th and was admitted to ICU. EKOS procedure performed on April 5th. Discharge diagnosis on April 7th: 1) Acute bilateral PE (Pulmonary Embolisms/Blood Clots) with significant right heart strain status EKOS cath directed thrombolytics on April 5th. 2) Extensive bilateral deep vein thrombosis. 3) Significant right heart strain confirmed on the echo 4) Mild anemia 5) Metabolic acidosis with mild hyponatremia 6) Hypercoagulable workup, most results pending at discharge 7) Acute hypoxic respiratory failure
COVID19 VACCINE	JANSSEN	1228553-1	65+ years	10-14 days	The patient presented to the emergency department with altered mental status, dry heaving, and body aches. She was found to have a partially occluding thrombus of the right cephalic vein consistent with venous thrombosis, as well as findings of thrombosis in the anterior segment branch of the right portal vein. She had a d-dimer of 25.77 increased to 35.2, and was thrombocytopenic with a platelet count of 92, which dropped to 36 the following morning. Platelets to present were: 92-36-32-23-19-28. The patient received the Johnson & Johnson COVID-19 vaccination two weeks prior to presentation.
COVID19 VACCINE	JANSSEN	1228569-1	50-59 years	10-14 days	Patient received their COVID vaccine on 4/7/21. Recently admitted for COVID (3/24/21 - 4/2/21) discharged on room air, doing well. Returned 4/17/2021 with acute onset and persistent right sided chest pain.
COVID19 VACCINE	JANSSEN	1228684-1	1-2 years	10-14 days	Patient admitted to Hospital 4/6-4/9 for bilateral lower back pain, fever, sore throat and leukocytosis. Diagnosed with a R iliofemoral nonocclusive thrombus present on admission. Ultrasound was performed and there was no evidence of an occlusive thrombus, there was evidence of flow through her previously placed stent. She was placed on a heparin drop and converted back to Xarelto at the time of discharge. Chest CT showed no evidence of PE. Of note, patient went on spring break and was out her Xarelto, missed approximate 4 days worth of medical. She was also diagnosed and treated for an acute strep throat infection.
COVID19 VACCINE	JANSSEN	1228855-1	18-29 years	10-14 days	28 y/o female with h/o obesity (120kg), anxiety and depression, received the J&J vaccine on 3/5/2021 (Lot 1805020). Home meds included only citalopram and an OCP which she had stopped on 3/10. On 3/15 she developed a predominantly R sided headache 9/10 pain, described as the worst of her life that didn't remit with over the counter analgesics and eventually became global in distribution, lasting 4 days. She was seen for this in urgent care on 3/19, given a shot of Toradol and then transferred to the emergency department where CBC showed platelets of 33, WBC 9.1 53% PMNs, 43% lymphs, Hgb 14.1, MCV 87, PT 15.7 INR 1.2. Chemistries were all normal. CT brain was unremarkable.
COVID19 VACCINE	JANSSEN	1229128-1	50-59 years	10-14 days	Presented with heahache Head CT showed dural sinus venous thrombosis currently treated with argatroban
COVID19 VACCINE	JANSSEN	1229208-1	65+ years	10-14 days	Patient urinated and passed a small blood clot. Happened once ten days after vaccination and then resolved. Patient had another episode 4/9/2021, passed small blood clot with urination, and again, resolved
COVID19 VACCINE	JANSSEN	1229262-1	65+ years	10-14 days	4/16/21 short of breath while gardening. Came to ER, diagnosed with Bilateral Pulmonary Emboli
COVID19 VACCINE	JANSSEN	1229547-1	65+ years	10-14 days	Came to ED on 4/15 with c/o anginal symptoms, found to be in rapid afib. EKG showed ST elevation in later precordial leads, went for emergent left heart catheterization. Went into V-fib arrest requiring defibrillation (x2) in addition to CPR in cath lab. Angio showed acute thrombotic occlusions of LM, LAD and RI, underwent mechanical thrombectomy of LM and LAD with balloon angio of RI (recent cardiac cath in March 2020 showed clearly patent stents). Placed on Impella bypass. Currently in CVICU care, intubated with Impella.

COVID19 VACCINE	JANSSEN	1229690-1	30-39 years	10-14 days	Janssen COVID-19 Vaccine EUA: patient presents to the emergency department (ED) reporting headache (10 out of 10 pain, difficult to keep eyes open) with neck pain, blurred vision, nausea, and photophobia for two weeks prior to arrival. Patient is four months post partum and breastfeeding. Patient diagnosed with cerebral venous sinus thrombosis and intraparenchymal hemorrhage. Admitted and underwent venous sinus thrombectomy. Currently still hospitalized.
COVID19 VACCINE	JANSSEN	1230024-1	50-59 years	10-14 days	Shortness of breath, hypoxia, Pulmonary Embolism, intubation death.
COVID19 VACCINE	JANSSEN	1230404-1	65+ years	10-14 days	Presented to Hospital for dyspnea. Diagnosed with large right sided pulmonary embolism; platelet count 138 T/UL at time of ER visit. Transfer to larger facility for higher level of care on 4/19/21.
COVID19 VACCINE	JANSSEN	1231260-1	30-39 years	10-14 days	I was contacted by physician assistant who informed us that patient was at HCF being treated for clotting believed to be secondary to having received the Janssen Covid19 vaccination. He said that she was diagnosed as having a focal dural venous thrombosis in the superior sagittal sinus and was being treated with Eliquis. He requested that we report this event to VAERS.
COVID19 VACCINE	JANSSEN	1231985-1	50-59 years	10-14 days	pt developed symptoms on 4/19/2021 after receiving shot on 4/7/2021. Patient was admitted to hospital and discovered to have a clot in left leg. Patient is receiving Lovenox.
COVID19 VACCINE	JANSSEN	1231997-1	65+ years	10-14 days	He developed a blood clot in his right arm.
COVID19 VACCINE	JANSSEN	1232777-1	50-59 years	10-14 days	pulmonary emboli Treatment-Xarelto just started treatment
COVID19 VACCINE	JANSSEN	1233121-1	50-59 years	10-14 days	Received shot on 3/12. Starting having pain in chest on 3/22. Was diagnosed with blood clots in the lungs on 3/26 via blood test and CT scan.
COVID19 VACCINE	JANSSEN	1233450-1	50-59 years	10-14 days	A week and a half after taking the Janssen COVID shot I had a knot and pain come up in my lower back. After going to the chiropractor two times the knot and pain ended up in my right leg. I then went to Urgent Care where they diagnosed me with a large blood clot. They sent me to imaging and after scanning the area confirmed that there was a blood clot in my right leg. Urgent Care then set me up with a specialist.
COVID19 VACCINE	JANSSEN	1233510-1	40-49 years	10-14 days	Death. Multiple pulmonary thrombi.
COVID19 VACCINE	JANSSEN	1233630-1	60-64 years	10-14 days	In the morning I noticed a pinching feeling in my lower right leg. I called my doctor to check on this. She sent me for an ultrasound of the leg on 04/15/2021. During a follow-up visit she informed me that it was a superficial blood clot and set up a second ultrasound on 04/28/2021 for confirmation that it had cleared.
COVID19 VACCINE	JANSSEN	1233818-1	50-59 years	10-14 days	Purple, looking like blood clots on the back of her leg
COVID19 VACCINE	JANSSEN	1234132-1	40-49 years	10-14 days	Blood clot in left leg, Found out on April 15 2021
COVID19 VACCINE	JANSSEN	1234170-1	40-49 years	10-14 days	We got a call from Doctor from ER to inform us that this patient came to the ER today & got swollen arm @ the injection site (left arm). They did the ultrasound & found there's a clot in brachial vein on the opposite arm (right arm). Doctor said they'll give pt Eliquis today.

COVID19 VACCINE	JANSSEN	1234257-1	18-29 years	10-14 days	a 27 y.o. female with a history of Covid infection December 26, 2020, positive covid test December 29, 2020. She had approximately 2 weeks of symptoms including generalized body ache and generalized weakness. Fatigue and some headache. Had some persistence of symptoms after that time. Had some benefit from ibuprofen. Was seen at emergency room on January 27, 2021 stating that she felt that all her symptoms of Covid had resolved except for some chest pain which awoke her on January 27. She presented to the emergency room. Had sinus tachycardia at 113 but otherwise unremarkable physical exam, laboratory studies with white blood count elevated 16,004-20, hemoglobin 13.7 g hematocrit 41.8%, MCV 87.1, RDW 12.7%, platelet count 329,000, segs 72.8%, lymphs 20.6%, monocytes 4%, eosinophils 1%, basophil 0.6%. BUN 10.1, creatinine 0.8, AST 24, ALT elevated 56, alkaline phosphatase 68, total protein 7.6, total bilirubin 0.3, albumin 3.6, globulin by subtraction 4.0, troponin less than 0.02, D-dimer quantitative 0.22, urine pregnancy test normal. Chest x-ray normal. Chest pain appears to be musculoskeletal and was reproduced by palpation of her chest wall. No evidence of deep venous thrombosis or pulmonary embolism. D-dimer was normal. Heart rate returned to normal after some intravenous fluids. Patient discharged on Zithromax 500 mg day 1 and then to 50 mg days 2 through 5. Also continued on ibuprofen. Received Johnson and Johnson vaccine April 5, 2021. Over the next week patient started having increasing soreness. Her joints hurt more than usual and her headache was worse. She had a sensation that her legs were ""numb and tingly"" starting at her buttocks and extending down her leg. Because of reported incidence of cerebral sinus thrombosis or cerebral vein thrombosis patient appropriately presented for screening in the emergency room and was sent for appropriate imaging. April 16, 2021 CT scan of head with and without contrast no acute intracranial hemorrhage, no mass-effect or midline shift. On contrast-enhanced images there appears to be a lobular nonocclusive filling defect in the far lateral right transverse sinus. Lobular occlusive filling defect is also likely present in the mid to central right transverse sinus. Short segment filling defect in the medial left transverse sinus. Remainder of sinuses and internal cerebral veins are patent. Focal lobular filling defect within the confluence of the right and transverse sinus most likely related to arachnoid granulation. No edema hemorrhage of the cerebellum or cerebrum. No other significant findings. April 16, 2021 confirmatory MRI angiogram of head without contrast with no restricted diffusion to suggest acute or subacute infarct. Contrast void in the middle to central right transverse sinus consistent with occlusive thrombus. Nonocclusive thrombus in the far lateral right transverse thrombus. Narrowing of the medial left transverse sinus without complete occlusion. April 16, 2021 2345 hrs. initial hematology consultation. D-dimer and fibrinogen levels have been requested stat and are still pending. If fibrinogen level is low will replace with cryoprecipitate. If D-dimer is elevated barely confirms diagnosis of possible vaccine related thrombosis. The fact the patient is not thrombocytopenic at this time is encouraging, however despite the lack of thrombocytopenia she still has clearly documented symptomatic nonocclusive and occlusive thrombus in her cerebral sinus. From UPtoDate.com Ad26.COVS.S (Janssen COVID-19 vaccine, also referred to as the Johnson & Johnson vaccine) ? On April 13, 2021, the US Food and Drug Administration (FDA) and Centers for Disease
COVID19 VACCINE	JANSSEN	1236583-1	60-64 years	10-14 days	PEA Cardiac Arrest tx with intubation, CPR, Epi prolonged mechanical ventilation, vasopressors, IVC filter, PEG, Trach. Now off of mechanical ventilation but still vented
COVID19 VACCINE	JANSSEN	1236923-1	65+ years	10-14 days	bilateral DVT confired with D-dimer and ultrasound. Treated with apixaban 5mg BID
COVID19 VACCINE	JANSSEN	1237091-1	50-59 years	10-14 days	Patient started having leg cramping on 4/13/2021, presented to the emergency department on 4/18/2021 with increasing shortness of breath and chest pain.
COVID19 VACCINE	JANSSEN	1237550-1	40-49 years	10-14 days	Cavernous sinus thrombosis per CT
COVID19 VACCINE	JANSSEN	1237947-1	65+ years	10-14 days	Patient admitted 4/12/21 with fatigue and abdominal pain. Found to have UTI but no definite sepsis, and acute renal failure. Treated with iv antibiotics and iv fluids. Over next 48 hours developed worsening encephalopathy and thrombocytopenia. MRI/MRA/MRV showed no acute findings. Hyperammonemia noted, with no known Hx of cirrhosis; US did not show portal vein or hepatic vein thrombosis. Encephalopathy worsened, no clear etiology; EEG just showed generalized encephalopathy. Renal function worsened. Patient became obtunded and was intubated 4/16/19. Platelet nadir of 31k. Dialysis started. Left common femoral DVT developed. Patient had DIC type picture. Respiratory failure worsened, hypotension developed, patient passed away 4/20/21. No clear etiology of encephalopathy and thrombocytopenia identified, unclear if related to J&J vaccine received 2 weeks prior.

COVID19 VACCINE	JANSSEN	1238260-1	65+ years	10-14 days	Patient received Janssen COVID19 vaccine on 3/18/21. The week of 4/12/21, patient noted right calf pain. No swelling or redness noted. Patient was seen in MD office on 4/21/21 and mentioned pain in right calf and that it was improving. MD ordered venous US and D-dimer and both tests were completed and resulted on 4/21/21. D-dimer is positive and venous US is positive for DVT in right gastrocnemius vein. Patient will start on Eliquis 10mg twice a day for 7 days, then Eliquis 5mg twice a day for 6 months. Will have Chest CT to rule out PE on 4/22/21.
COVID19 VACCINE	JANSSEN	1238463-1	50-59 years	10-14 days	3/26 office appointment: New onset right and left sided chest pain with associated shortness of breath, fatigue and intermittent lightheadedness. Labs drawn. CT scan showed Scattered small occlusive and nonocclusive emboli within small distal pulmonary artery branches bilaterally. Started on apixaban. Has appointment with Hematology on 4/29
COVID19 VACCINE	JANSSEN	1238488-1	65+ years	10-14 days	Patients daughter reported her mother had a stroke (cerebral thrombosis). Patient was admitted to hospital on 3/28/21. Patient has surgery and was admitted to the ICU. Patient also has rehabilitation. Patient is currently recovering at home .
COVID19 VACCINE	JANSSEN	1238784-1	50-59 years	10-14 days	Pulmonary Embolus
COVID19 VACCINE	JANSSEN	1239209-1	60-64 years	10-14 days	DVT left leg, pt put on Eliquis by hospital ER
COVID19 VACCINE	JANSSEN	1239455-1	50-59 years	10-14 days	DVT in lower left leg
COVID19 VACCINE	JANSSEN	1240708-1	40-49 years	10-14 days	Delayed menstrual cycle by 4 days, when started very painful and heavy. Much more clots than usual and lasting longer than usual. Uncomfortable enough to require rest. Still going heavy when it should be tapering off.?
COVID19 VACCINE	JANSSEN	1242090-1	40-49 years	10-14 days	Developed symptoms of pain, redness, swelling to left anterior shin on 4/13, symptoms worsening so presented to clinic for evaluation. Has multiple varicose veins in this area.
COVID19 VACCINE	JANSSEN	1242576-1	65+ years	10-14 days	DVT Left lower extremity, pain developed about 10 days after vaccine, diagnosed 4/19/21 on Ultrasound, no prior history
COVID19 VACCINE	JANSSEN	1242632-1	60-64 years	10-14 days	extensive bilateral PE
COVID19 VACCINE	JANSSEN	1242683-1	50-59 years	10-14 days	Deep Vein Thrombosis- occlusive and non-occlusive in R axial and R brachial veins at level of PICC line. Pt admitted to hospital on 4/18/21 with acute basal ganglia hemorrhagic CVA, with PICC line placement on admission. DVTs identified on 4/21 via ultrasound. Pt currently admitted to Hospital

COVID19 VACCINE	JANSSEN	1242735-1	18-29 years	10-14 days	ED NOTE is as follows...from 4/21/21 @ 21:47 a 28 y.o. male who to the emergency room with reports of a headache for the last 48 hours. He reports this as being one of the worst headaches he has ever had. He was seen at urgent care and given Toradol, Zofran and Benadryl and still rates his pain an 8 out of 10. He does feel pressure behind his eyes. And reports vomiting in the parking lot at urgent care. He denies abdominal pain back pain, neck pain, shortness of breath, chest pain, numbness or tingling or any other worsening concerns. Reports that he did receive a recent Johnson & Johnson vaccination. Patient states he does vape. He occasionally drinks alcohol he denies any illicit drugs. Patient denies any head trauma. Diagnosis management comments: This is a 28-year-old male arrives to the emergency room with reported migraine headache for the last 48 hours. He did report that he was go to urgent care in which he received a migraine cocktail of Zofran, Benadryl and Toradol. Patient reported that his headache was not resolved so urgent care sent him on for further evaluation. Patient upon arrival had a negative neurological exam however he did report that he had pressure behind his eyes. Was unable to see any papilledema on fundoscopic exam. Check patient's pressures bilaterally and they were 21 and 18. Patient did report to me that this was the worst headache of his life. I did administer IV fluids here as well as Tylenol and morphine. Patient did report some improvement. Patient did report in his past medical history had a recent Johnson & Johnson vaccination. A CBC and CMP was obtained. Did have thrombocytopenia with a count of 66. Since my exam was PERRL with normal extraocular movements. He had no eye redness or eye pain. Of low concerns for any iritis or uveitis. Patient's patient CT of his head did show a abnormal CT that had a dense appearing superior sagittal sinus that was representing a venous thrombosis. Radiologist did recommend a MRI MRV. An MRI and MRV was ordered. Patient MRI MRv did show findings are consistent with a venous thrombosis involving the right jugular right transverse sinus and superior sagittal sinus there is also a patchy edematous change within the subcortical white matter areas bilaterally and symmetrically. There was no CVA. With patient's reported migraine headache. Reported blurred vision, low platelets, recent vaccination I do believe patient has vaccine induced thrombotic thrombocytopenia. With this finding I did converse with my overseeing physician Calls were made out to neurology and then a call out did prefer to have patient started on IVIG at 1 g/kg daily for 2 days and blood thinner Xarelto 15 mg p.o. twice daily. These orders were initiated. Internal med services was consulted and with conversations of family, internal med services out possible transfer that an interventionalists could be available if patient needed it. Report was given at 2100 upon my end of shift.
COVID19 VACCINE	JANSSEN	1242815-1	40-49 years	10-14 days	left leg arterial embolus, treated with percutaneous embolectomy
COVID19 VACCINE	JANSSEN	1243194-1	60-64 years	10-14 days	Patient had the Janssen vaccine as noted. He presented with significant superficial clot in the lower leg. Ultrasound read Mixed partially occlusive and occlusive superficial venous thrombosis in the right greater saphenous vein. This originates 2.2 cm from the junction with the right common femoral vein. He presented with 2 days of leg swelling without clear trigger such as travel, trauma etc.
COVID19 VACCINE	JANSSEN	1243975-1	40-49 years	10-14 days	Pulmonary embolism symptoms felt April 12, 13. Pulmonary infarction felt night of April 15th forward. Blood test was positive for possible clots done April 16th. CT/CTA chest scan done at hospital (also April 16th) confirmed the above embolism and infarction. Blood thinner via shots, then via tablet (Xarelto) until discharge on April 17th. Continuing on Xarelto.
COVID19 VACCINE	JANSSEN	1245227-1	65+ years	10-14 days	My Mom received the J&J Vaccine. Apprx 10 days later fell, fractured hip, Surgery April 3rd - On April 5th doctor at medical center said she has a blood clot and low platelets. Was in Hospital from April 2 to April 12th
COVID19 VACCINE	JANSSEN	1245230-1	40-49 years	10-14 days	Patient received J&J COVID vaccine on 4/9/21 at pharmacy . Today (4/22/21), patient is admitted to our facility with VTE, submassive, unprovoked, with bilateral high-burden PE and LLE DVT, and right heart strain / acute cor pulmonale; in patient with H/o R PE, provoked 2014 after transcontinental flight, s/p Warfarin x 6 months, reportedly negative hypercoagulable panel; with strong family history of venous thrombosis in mother and sister. Heparin drip started, plan to start DOAC tomorrow. Anticipate hospital admission for at least 2 nights.

COVID19 VACCINE	JANSSSEN	1245290-1	50-59 years	10-14 days	Multiple pulmonary embolisms in bilateral lungs with lung infarct, superficial blood clot in the right groin area, significant right abdominal pain, shortness of breath, low oxygen saturation levels admitted 3 days in the hospital. 36 hours of Lovanox injections followed by transition to Eliquis 10 mg twice per day, respiratory exercises, oxycodone given for pain Pain has diminished in lower right lung area, clotting appears to be under control
COVID19 VACCINE	JANSSSEN	1246636-1	65+ years	10-14 days	Patient received vaccine on 11 March and developed a superficial venous cord on same arm extending from the left axillary region beyond the left elbow. US of the extremity is pending to rule out DVT of the upper extremity.
COVID19 VACCINE	JANSSSEN	1247700-1	40-49 years	10-14 days	Shortness of breath for several days, feeling fatigue and week, pain in right elbow Diagnosed Apr. 17 in ER setting: acute segmental and subsegmental pulmonary embolism without acute cor pulmonale Acute thrombosis of superficial vena basilica right arm
COVID19 VACCINE	JANSSSEN	1247878-1	40-49 years	10-14 days	Patient states he was doing well until 419 when he had abdominal pain. Patient says abdominal pain started in the middle of his belly and radiated to his back. Pain is worse when he tries to eat and 8 out of 10. Pain is sharp. Patient has not had pain like this before. Pain improved when not eating. Patient has had watery non-bloody diarrhea for the past 2 days. Patient denies any fevers or chills.
COVID19 VACCINE	JANSSSEN	1248235-1	50-59 years	10-14 days	Pain and swelling in Left Calf muscle. Treating the blood clot with Xeralto
COVID19 VACCINE	JANSSSEN	1248429-1	65+ years	10-14 days	Patient came to ED with complaints of syncopal episode. passed out, hit her head, felt mildly short of breath with ambulation.
COVID19 VACCINE	JANSSSEN	1248552-1	65+ years	10-14 days	Developed severe right leg pain within two days after the vaccine. She had confirmed deep venous thrombosis on ultrasound confirmed on 4/23/21 without other known provocation.
COVID19 VACCINE	JANSSSEN	1249109-1	30-39 years	10-14 days	Pulmonary embolism. Chest pain, shortness of breath, rapid heart rate.
COVID19 VACCINE	JANSSSEN	1250901-1	65+ years	10-14 days	Blood clots in each lung and leg
COVID19 VACCINE	JANSSSEN	1251038-1	18-29 years	10-14 days	Initial severe headache after vaccine- this resolved in 24-48 hours. Had some LEFT flank pain for a few days. This resolved on its own. Then awoke on 4-17-2021 with LEFT calf pain that was constant and persistent. Called triage on Monday 4-19-2021 for guidance- came to Urgent Care. D dimer done and was positive. Was then sent to ER for imaging with + Doppler U/S LLE DVT- started on Eliquis.
COVID19 VACCINE	JANSSSEN	1251176-1	30-39 years	10-14 days	1) Bilateral acute appearing pulmonary embolism right greater than left, clot burden moderately large. 2) . Probable portal vein thrombosis with partial superior mesenteric vein thrombosis. 3) Changes of mild diffuse colitis are suspect. Potential etiologies for colitis includes infectious processes, inflammatory processes, as well as ischemic etiologies. 4) Splenomegaly. 5) Thrombocytopenia. Platelets of 39000
COVID19 VACCINE	JANSSSEN	1251240-1	65+ years	10-14 days	13th of April. I had a blood clot in my hand. My index finger on my left hand was numb and black and blue all around the knuckle area and into my hand area. I went to my primary care - I went to the acute center there. She said the hand was cold and could see the black and blue. They put me on Plavix for 30 days and I haven't had any reoccurrence of that. I think it was the 21st, I couldn't sleep all night, I had a kidney stone - the pain was so bad I got nauseous - around my back and side and in my front. I didn't have a fever. I went to the doctor office and they checked urine - and said there was blood in the urine. I was prescribed - Tamsulosin HCL. They thought I had passed most of it by the time I got there.
COVID19 VACCINE	JANSSSEN	1251454-1	30-39 years	10-14 days	Headache== Found to have venous sinus thrombosis on CT and MRI
COVID19 VACCINE	JANSSSEN	1255977-1	30-39 years	10-14 days	On 4-20-2021 I felt a deep pain in my lower left leg that increased until I went to the hospital on 4-22-2021. The pain is a deep throbbing pain that has caused swelling to where I cannot feel most of my left foot. I went to the hospital around 3 p.m. and they found I have Deep vein thrombosis of distal end of left lower extremity.
COVID19 VACCINE	JANSSSEN	1256056-1	50-59 years	10-14 days	Left lower leg edema present with tight calf up to thigh Given Enoxaparin 60mg bid x 5 days then Pradaxa 150mg thereafter
COVID19 VACCINE	JANSSSEN	1256511-1	50-59 years	10-14 days	Left lower medial aspect swelling , warmth and thrombosis noted. Placed on Naproxen 500mg BID Compression stockings Heat and Cold compresses

COVID19 VACCINE	JANSSSEN	1256715-1	30-39 years	10-14 days	During my menstrual cycle I usually have no symptoms other than tender breasts. So these symptoms were very unusual. Leg pains, pain and pressure in pelvis, ditoral pain, pain around vaginal opening, stinging like acid during urination that sent a shock through my entire body, uncontrollable bladder, nausea, large blood clots, lower stomach pain, flank pain, hot/cold chills, if I touch my belly button the pain radiated to my vagina, ovaries hurt, cervix pain, dryness, unable to get comfortable, crawling out of my skin, and constant urge to urinate, depression. I landed myself in the ER where they told me to take Tylenol and Motrin and sent me on my way. These medications were not able to control the amount of pain I was in. I have now reached out to a couple specialists.
COVID19 VACCINE	JANSSSEN	1257862-1	40-49 years	10-14 days	per Clinic Visit: date of visit: 4/16/21 Calf pain 4-5 days after received Janssen vaccine, got evaluated 2 weeks later. Positive for distal DVT, normal CBC. No other risk factors for DVT.
COVID19 VACCINE	JANSSSEN	1257910-1	40-49 years	10-14 days	My first menstrual period following the vaccine was exceedingly heavy in flow for the first two days, which is atypical for me. Heavy clots of menstrual discharge were observed. It is not yet known whether these side effects will continue for my next menstrual cycle. Lesser effects followed two days after the vaccine with fatigue, sore arm, armpit, and glands in the injection arm. These side effects dissipated by day 3 status post vaccine administration.
COVID19 VACCINE	JANSSSEN	1258089-1	30-39 years	10-14 days	Client complained of pain and swelling in right calf area 2 -3 days before going to ER , at ER. Doppler study confirmed popliteal DVT
COVID19 VACCINE	JANSSSEN	1258576-1	65+ years	10-14 days	Heart went into Atrial fibrillation causing blood clotting. He has no prior heart condition. A blood clot traveled to his brain causing a Posterior Cerebral Artery Stroke. He has been in ICU since 04/22/2021.
COVID19 VACCINE	JANSSSEN	1262540-1	50-59 years	10-14 days	blood clot in my left eye, swelling of the eye and under the eye. headaches at the base of my skull so bad nothing helped. Joint pain so bad I couldn't walk for 2 days.
COVID19 VACCINE	JANSSSEN	1262688-1	60-64 years	10-14 days	Patient was driving on 3/24 when her vision became blurry in her left eye. She saw her eye doctor on 4/21 and was sent to a specialist. On 4/23 she was diagnosed with a blood clot in her left eye. She is to begin eye injections for treatment.
COVID19 VACCINE	JANSSSEN	1263150-1	40-49 years	10-14 days	Deep venous thrombosis at the site of vascular access line-Initially started on heparin, now switched to Rivaroxaban Thrombocytopenia-Supportive treatment and monitoring
COVID19 VACCINE	JANSSSEN	1263254-1	60-64 years	10-14 days	Blood clot in left calf muscle
COVID19 VACCINE	JANSSSEN	1263365-1	30-39 years	10-14 days	30yo female has been on combination oral contraceptive for 15 years, no PMH, no person/family hx of VTE. 2 weeks prior received Johnson & Johnson COVID vaccine, 2 days later develops bilateral calf pain which progressed until 3 days prior to Emergency Dept arrival when PCP ordered ultrasound, showed non-occlusive DVT in the left common femoral vein and no right leg DVT. Non-smoker. D-dimer 0.32 ug/mlFEU, platelets normal at 269k. Treated by starting apixaban and stopping combination oral contraceptive, discharged home from Emergency Dept with follow-up.
COVID19 VACCINE	JANSSSEN	1263595-1	50-59 years	10-14 days	Pt. developed right lower medial leg pain on Friday. She states the pain radiated up her leg and she felt there was warmth to the area. She denies injury. She states she had the J&J covid vaccine two weeks ago and has concerns of a DVT. There is minimal swelling and ecchymosis in the area. There is no redness or warmth noted. There is no tenderness, redness or warmth noted in her calf area. She has good pedal pulse and good capillary refill of her nail beds. She has no significant PMH and denies any recent air travel, long car rides or prolonged sitting. She states she is active.
COVID19 VACCINE	JANSSSEN	1263940-1	40-49 years	10-14 days	Janssen COVID-19 Vaccine EUA: two weeks after vaccination patient reported to an urgent care with right leg swelling and headache. Two days later patient presented an emergency department, diagnosed with left lower extremity deep vein thrombosis (DVT) and bilateral pulmonary emboli (PE). Transferred to current hospital for management including anticoagulation with a direct thrombin inhibitor, intravenous immune globulin (IVIG), and additional laboratory testing.
COVID19 VACCINE	JANSSSEN	1264036-1	50-59 years	10-14 days	immediately following vaccine patient developed chills and headache. Headache has continue to this date. 4/22/21 developed chest pain went to the emergency room and was diagnosed with a bilateral pulmonary embolism.

COVID19 VACCINE	JANSEN	1264060-1	40-49 years	10-14 days	Patient evaluated in ED 04/26 for bilateral leg cramping, swelling that started just over a week prior. Reviewed records from that visit. Work up was significant for bilateral lower extremity DVTs and thrombocytopenia. Patient was started on Xarelto at that time. Patient does not have any significant risk factors for blood clots. He is not obese, denies tobacco use, recent procedures, recent travel, prolonged immobility, family history of bleeding or clotting disease, etc. He is up to date on cancer screenings based on age/family hx. He did receive the Johnson and Johnson vaccine on 04/07.
COVID19 VACCINE	JANSEN	1265163-1	30-39 years	10-14 days	Blood clot in each lung, chest pain, labored breathing, leg pain and upper back pain.
COVID19 VACCINE	JANSEN	1266101-1	50-59 years	10-14 days	Vaccine- Induced Thrombotic Thrombocytopenia Portal and hepatic vein thromboses Diabetic Ketoacidosis
COVID19 VACCINE	JANSEN	1266405-1	65+ years	10-14 days	Patient received J&J COVID vaccine on 4/10/2021. She underwent elective R total knee arthroplasty on 4/20/2021. On 4/21, patient developed chest pain and was found to have a STEMI (large embolus in the posterolateral branch of the right coronary artery). She underwent thrombectomy and angioplasty on 4/21 with no evidence of CAD elsewhere. She developed hypoxic respiratory failure evening of 4/21 and was found to have bilateral pulmonary embolus with saddle type emboli and distal emboli throughout both lungs. She underwent IR guided thrombectomy on 4/22 and had a cardiac arrest intra-operatively. Given timing of onset and recent J&J COVID vaccination, the patient was treated with IVIG, steroids, and placed argatroban. She continued to have multiorgan failure requiring mechanical ventilation and hemodialysis. On 4/26, CT head was positive for small area of subarachnoid hemorrhage. Patient was transitioned to comfort care measures and palliatively extubated on 4/26.
COVID19 VACCINE	JANSEN	1266651-1	65+ years	10-14 days	Patient developed shortness of breath, chest pain 'fuzzy head,' headache, rhinorrhea, diarrhea, and increased fatigue around 3/28/21 had clinic appointment 3/30/21, diagnosed with pneumonia. XR CHEST 2 VIEWS (PA AND LATERAL), TRANSTHORACIC ECHO (TTE) ADULT NON CONGENITAL, EKG 12-LEAD completed. given ceftriaxone (ROCEPHIN-Equivalent) injection 1,000mg IM, and doxycycline monohydrate (MONODOX) 100 mg capsule PO. was evaluated in ED 4/5/21 CT Abdomen Pelvis with IV Contrast Final Result 1. Positive for extensive acute bilateral pulmonary emboli at the lung bases as detailed in the body of the report. DX Chest Portable 1 View Final Result Mild left ventricular prominence is noted. Small right pleural effusion is seen. Minimal discoid atelectatic changes in the left perihilar region and left lung base. Elevated right hemidiaphragm suggests eventration. Admitted to Hospital 4/5/21, per admission diagnosis: Acute pulmonary embolism (*) submassive likely secondary to covid 19 Per hospital course notes: Patient presented with acute hypoxic respiratory failure and was show to have submassive PE with severe pulmonary hypertension seen on TTE. He should be on lifelong therapy given 2nd VTE and severity. I would consider unprovoked (COVID in 11/20 wouldn't count I wouldn't think). He was started on eliquis 10 mg BID x 7 days than 5 mg bid. Given his severe pulm htn on TTE, left atrial pressure normal. We would have outpatient sleep study as well He will need VQ scan to assure no CTEPH. Will have outpatient follow up. We discontinued his aspirin on discharge as well.
COVID19 VACCINE	JANSEN	1266689-1	65+ years	10-14 days	BLOOD CLOTS IN BOTH LUNGS. SHORTNESS OF BREATH. UPPER BACK PAIN. WEAKNESS. SWEATING AND COLD. NO COLOR IN FACE -- GREY. LOSS OF EYE SIGHT -- STARTED WITH BLURRED VISION.
COVID19 VACCINE	JANSEN	1267264-1	40-49 years	10-14 days	I have a major blood clot in my left leg. I had two ultrasounds and now starting blood thinners.
COVID19 VACCINE	JANSEN	1267579-1	65+ years	10-14 days	4/19/2021: Woke up in the middle of the night with an achy arm. Had this for a week. Went to chiropractor as she thought it was neck trouble. Chiropractor states arm is swollen and see MD. MD sent patient for ultrasound and blood clot confirmed in right arm pit. Patient started on eliquis.
COVID19 VACCINE	JANSEN	1268216-1	60-64 years	10-14 days	Patient received Janssen vaccine on 4/12 and developed left arm pain a few days later. Presented to the ED with left arm swelling 10 days after vaccination and was found to have a left upper extremity DVT.
COVID19 VACCINE	JANSEN	1268639-1	30-39 years	10-14 days	pt developed symptoms of left leg swelling on 4/22/21 with increased pain and fullness in lower leg. found at ER on unspecified date to have a acute DVT, started on Xarelto, and fu in clinic on later unspecified date - with cbc normal, cmp normal goal of 3months of AC and hematology consultation
COVID19 VACCINE	JANSEN	1271796-1	50-59 years	10-14 days	Hospital called at 4:00 PM on 4/29 to let us know that the patient was being admitted due to several small PEs.

COVID19 VACCINE	JANSEN	1272700-1	40-49 years	10-14 days	Patient received the Janssen COVID 19 Vaccine on 04/07/2021. No physical adverse assessment findings observed during the post-vaccine administration observation period. During the observation period, the patient verbalized that she was ""feeling fine and had taken an Alive(medication)"". Patient was later seen, after the observation period and engaged in a discussion stating that she ""continued to feel okay but felt a little queasy (confirmed as nauseated)"" and denied additional symptoms requiring immediate medical attention. On 04/29/2021, patient informed the clinical nursing team at the administering facility that she experienced adverse side effects 13 days after receiving the vaccine and was hospitalized on 04/20/2021 - 04/24/2021. Patients adverse side effects related to the vaccine are self-reported as blood clotting. Medical documentation not provided. The vaccine administering facility's clinical staff is not unable to be verified by and confirm are deny adverse medical findings at the time of this dictation. Please contact patient for the selected healthcare provider where care was rendered for detail specific related adverse medical event. ""
COVID19 VACCINE	JANSEN	1273203-1	50-59 years	10-14 days	Severe headache followed by abdominal pain, eventually confirmed portal vein thrombosis (fully blocked), treated as TTS with hospitalization for 5 days
COVID19 VACCINE	JANSEN	1273276-1	18-29 years	10-14 days	19 y.o. female with h/o Hashimoto's thyroiditis now admitted 4/29/2021 with cerebral venous thrombosis. She received J&J COVID vaccine on 4/12.
COVID19 VACCINE	JANSEN	1273633-1	30-39 years	10-14 days	Left posterior leg/knee pain started on 4/26. DVT left leg diagnosed via ultrasound, started on Xarelto
COVID19 VACCINE	JANSEN	1273784-1	50-59 years	10-14 days	Patient received his dose of COVID-19 Janssen vaccine on 4/5/21. Patient was not previously COVID-19 positive and did not have any predisposing factors(PMH, allergies, etc.) for experiencing an adverse drug event. The ADR did not occur at the time of the administration of the vaccine. On 4/16/21 patient began to have swelling in his neck to his hand and presented to the ER. Patient reports having recent tooth surgery complication and thinks the appearance of swelling occurred on same side and occurred around same time. Patient was diagnosed with a DVT of the internal jugular, subclavian vein and given a dose of lovenox. Patient had personal matters to attend to and left AMA before full treatment and disease workup. Patient presented the next day on 4/17/21 to MC to receive further care. The swelling had worsened overnight. Labs showed normal platelet count and no thrombocytopenia. Ultrasound confirmed a near-occlusive right internal jugular and subclavian DVT. An asymptomatic cerebral venous thrombosis, with thrombosis in the right sigmoid sinus and partial thrombosis of the right transverse sinus was also noted on imaging. MC notes state usual cause for upper extremity DVT does not apply to patient - no trauma or evidence of cancer. Patient suffered no significant events during hospitalization. Clot was further treated with Argatroban during stay and patient was d/c on 4/20/21 with Apixaban to treat the DVT with plans to follow up with vascular surgery for surgery after clots are resolved in several weeks
COVID19 VACCINE	JANSEN	1273816-1	18-29 years	10-14 days	24-year-old male patient with no past medical history received Johnson & Johnson Covid vaccine on April 7 presented to ED with abdominal pain and was found to have portal vein, splenic vein, superior mesenteric vein thrombosis. Patient was also found to be thrombocytopenic he was admitted to the stepdown unit placed on bivalirudin. Patient remains hospitalized at the time of this report.
COVID19 VACCINE	JANSEN	1274563-1	30-39 years	10-14 days	On April 16, 2021 (Day 13 after Vaccine) I was diagnosed with acute deep vein thrombosis (DVT) of my femoral vein in my left leg by Hospital. In other words, I was diagnosed with a blood clot in my upper left leg. Pain in both my legs had started on April 13, 2021 (Day 10 after Vaccine). On April 16, I had a virtual appointment with my doctor who prescribed an ultrasound to rule out DVT. I went to an ultrasound appointment at Radiology at 3:30pm where a blood clot was found in my left leg. I was admitted into the emergency room at Hospital and prescribed medication and follow ups from there...
COVID19 VACCINE	JANSEN	1274572-1	30-39 years	10-14 days	On April 16, 2021 (Day 13 after Vaccine) I was diagnosed with acute deep vein thrombosis (DVT) of my femoral vein in my left leg by Hospital. In other words, I was diagnosed with a blood clot in my upper left leg. Pain in both my legs had started on April 13, 2021 (Day 10 after Vaccine). On April 16, I had a virtual appointment with my doctor who prescribed an ultrasound to rule out DVT. I went to an ultrasound appointment at Radiology at 3:30pm where a blood clot was found in my left leg. I was admitted into the emergency room at Hospital and prescribed medication and follow ups from there...
COVID19 VACCINE	JANSEN	1275233-1	40-49 years	10-14 days	Pt had headache for the last week. J&J vaccine on 4/10, dxed with cerebral venous thrombosis. Pt's age is 47, not 46. Form would not allow me to put in pt's age and cited an error with pt's DOB.

COVID19 VACCINE	JANSSEN	1278070-1	65+ years	10-14 days	UTI 3/16/2021-3/20/2021. UTI 4/28/2021. Sensitivity to light 3/24/2021 - current. Blurry Vision 3/20/2021 - 3/24/2021. Partial blindness 4/04/2021 - current. Headaches 3/24/2021 - current. Doctor ruled not a stroke. Stroke of the eye due to blood clot or plaque build up is the highest suspected cause. No previous incidents of this nature had occurred.
COVID19 VACCINE	JANSSEN	1280064-1	65+ years	10-14 days	4/13/2021 heartburn like symptoms started. 4/20/2021 admitted to emergency room, received diagnosis of 3 blood clots in the heart, 4/27/2021 died as a result of blood clots in heart
COVID19 VACCINE	JANSSEN	1281688-1	65+ years	10-14 days	pulmonary embolism
COVID19 VACCINE	JANSSEN	1281880-1	60-64 years	10-14 days	4/25/2021 - He was apparently well until 2 days prior to admission when he developed spontaneous left calf pain and swelling. He denies any associated trauma, recent travel and immobility. He is not taking any new prescription, including steroids. One day prior to admission, he started experiencing left-sided pleuritic chest pain up to 9/10 in intensity and exertional shortness of breath. He denies any fevers, hemoptysis, sputum production, diaphoresis, nausea, vomiting, abdominal pain, dizziness or lightheadedness. The pain was persistent throughout the day. Today, his chest pain persisted and his shortness of breath had progressed. He also noted left arm swelling with mild discomfort. He felt that his left leg swelling and pain had improved today. Nevertheless, given persistent symptoms, he decided to come to the emergency room for further evaluation management. In the emergency room, his initial blood pressure was 218/104 with mild tachycardia of 99, normal oxygen saturation and no fevers. CBC showed a white count of 12.35, hematocrit of 50.4 and normal platelet count 198. INR was normal at 1.06. BMP showed mild hyperglycemia at 148. Troponin was 5 and BNP was 8. Imaging studies show extensive left upper extremity DVTs that involved the left subclavian vein, left lower extremity DVTs and bilateral lower lobe pulmonary emboli. 4/30/2021 Presumed unprovoked extensive DVT of the left upper extremity and left lower extremity. However, he did recently receive Johnson & Johnson Covid vaccine. Now status post catheter directed thrombolysis to the left upper extremity.
COVID19 VACCINE	JANSSEN	1289927-1	65+ years	10-14 days	Patient was discharged from the hospital after massive PE. She went to the hospital at 2am last Saturday. Patient described unbelievable pain from shoulder neck and arms. She could hardly walk to her car. Went to ER. There they ran tests and found many blood clots in lungs. Blood clots had stopped the blood in that area. They were not definitive but said it sounded like that. Got a breathing apparatus after because it's been hard to breathe and she has been shaky. Her shot was administered 04/12 during chemo. Hospital April 24. She was discharged and given a blood thinner and pain medication - Oxycodone & Eliquis.
COVID19 VACCINE	JANSSEN	1290875-1	65+ years	10-14 days	Pulmonary embolism. Had surgery to remove blood clots in lungs
COVID19 VACCINE	MODERNA	0937518-1	30-39 years	10-14 days	LEFT FACIAL SWELLING WITH LARGE AMOUNT OF NASAL BLEEDING AND CLOTTING. SHE SAW HER PCP AND HAD LAB TESTING AND GIVEN BENEDRYL. SHE WILL F/U WITH PCP AGAIN TODAY.
COVID19 VACCINE	MODERNA	0989737-1	30-39 years	10-14 days	Received vaccine on 1/4. Started menstrual cycle on 1/16 which was 1 week early. 3 days into the cycle, heavy vaginal bleeding with large blot clots (golf ball size) starting on 1/20/201 and continuing until now 1/31, bleeding still going on.
COVID19 VACCINE	MODERNA	0991693-1	30-39 years	10-14 days	I fell the pain in my leg immediatley the next day and was limping all day fromt hat point on. Deep Vein Rhrombosis (DVT) in right leg knee.
COVID19 VACCINE	MODERNA	1013048-1	50-59 years	10-14 days	Patient was admitted to the Hospital with dx of a Pulmonary Embolus 2/9/21 Above named Hospital
COVID19 VACCINE	MODERNA	1024515-1	40-49 years	10-14 days	Developed bi lateral pulmonary embolisms (multiple) and pneumonia in left lung
COVID19 VACCINE	MODERNA	1030447-1	40-49 years	10-14 days	02/04/21-groin pain/burning, buttocks and thighs muscle tightness, unable to sit for extended period of time due to groin discomfort 02/05/21-continued groin pain, new bilateral arm/bicept muscle pain with right side worse than left 02/06/21- headache, loss of appetite, chills, shoulder/neck/jaw/hips joint pain 02/07/21-back and ribs pain with sitting or lying- unable to sleep due to extreme pain, unable to transition from lying to sitting to standing due to pain, fever 101.8, worsening of all symptoms. Employee Health contacted, instructed to obtain Covid test, results negative. 02/08/21-First day missed work. Continued worsening of pain, groin and hip pain radiating down the back of both legs to back of both knees 02/09/21- Excruciating pain, difficulty with ambulating. Seen at Emergency Department, labs and imaging obtained, informed of bilateral Pulmonary Embolisms, admitted for treatment.

COVID19 VACCINE	MODERNA	1048882-1	65+ years	10-14 days	Vaccine was administered 2/1/2021 at approximately 9am. Due to self reporting of allergic reaction (hives) to Augmentin, patient was monitored on site for 30 minutes. After the monitoring period, she was cleared to go with no issues reported at the time. We were later informed that the patient passed away from a pulmonary embolism on 2/12/2021.
COVID19 VACCINE	MODERNA	1066556-1	65+ years	10-14 days	Stroke, Pulmonary embolism, kidney failure
COVID19 VACCINE	MODERNA	1081909-1	40-49 years	10-14 days	DVT blood clot and surface blood clot in lower left leg diagnosed at the ER on 2/12/21. Levonox injections and warfarin have been started. Twice weekly INR checks. No longer need the injections; warfarin is continued. Next INR check is scheduled for Thursday March 11, 2021. Warfarin may need to continue life-long.
COVID19 VACCINE	MODERNA	1090965-1	65+ years	10-14 days	Patient is a very pleasant 80 year old female with a history of hypertension and recent pelvic fracture approximately two months ago who presented to the emergency department reporting right sided chest pain. She states that her symptoms started on Sunday. She has pain with a deep breath and also with exhaling. She reports it is a sharp pain. She states that she has had no lower extremity edema or calf pain, however, she did have a shooting pain down her right leg recently. She denies any history of personal or family history of deep venous thrombosis or pulmonary embolus. She reports that she has not had any hemoptysis. She denies feeling short of breath. She denies abdominal pain, nausea, vomiting, or diarrhea. She states that she has not had any COVID exposures or known symptoms. She has received two COVID vaccine doses. She reports that she has not been sick and denies fever, chills, or cough. In the emergency department she was diagnosed with an acute pulmonary emboli in the right main pulmonary artery with extension into the segmental pulmonary arteries. There is concern for early pulmonary infarct. This has prompted admission to the hospital.
COVID19 VACCINE	MODERNA	1091169-1	65+ years	10-14 days	ACUTE STEMI HEART ATTACK - VENTRICULAR FIBRILLATION - 99.9% BLOOD CLOT IN RIGHT CORONARY ARTERY
COVID19 VACCINE	MODERNA	1095435-1	50-59 years	10-14 days	Headache, nausea on 1/25 progressed to SOB 1/26 and death 1/27
COVID19 VACCINE	MODERNA	1097013-1	65+ years	10-14 days	Saddle blood clot in lung. Place in ICU for 1 day. Then regular room. Heparin drip to Apixaban. No activity. All medical tests indicated no cause of blood clot. Vitals great. Past out twice and threw up night it started
COVID19 VACCINE	MODERNA	1098715-1	65+ years	10-14 days	My 1st Covid-19 vax was on Saturday 02/13/2021. On Friday 02/26/2021 I had pain in my right ankle and foot and thought it was possibly just another bruise. Saturday evening 02/26/2021 I realised it was a blood vessel popping out. On Tuesday 03/02/2021 I had an ultrasound and it was diagnosed as a ""superficial thrombosis"". It goes from the inside of my right foot to the top of the foot. Then it can be seen on the inside of my ankle, skip a spot, and is again visible on the inside of my calf. It ends mid-calf on my right leg.""
COVID19 VACCINE	MODERNA	1100869-1	65+ years	10-14 days	Symptoms= extreme short of breath and elevated heart rate. Time = 13 days after 1sr dose vaccine symptoms started. Went to ER on January 30th. CT scan showed bilateral pulmonary emboli. Doppler showed no sign of DVT. Negative COVID and chest X-ray was clear. ECHO cardiogram showed right heart distress. Treatment= IV Heparin followed by IM Lovenox. ICU X 2days and released to home on Eliquis BID. Follow up with Hematologist and cardiologist.
COVID19 VACCINE	MODERNA	1104379-1	65+ years	10-14 days	shortness of breath and fatigue
COVID19 VACCINE	MODERNA	1104554-1	65+ years	10-14 days	I had quite an adverse reaction to the second MODERNA vaccine. That afternoon and evening I developed symptoms. I was experiencing chills, fever, body aches, headache, sore throat, shaking and nausea. As the week went on, my reaction became worse. I was sweating profusely and had shortness of breath accompanied with burning pain on the top of my hands and feet and a rash. On Friday morning, 5 days after the vaccine, I collapsed and had a stroke. I was rushed to hospital and was admitted. It was confirmed that I had a stroke. through a Cat Scan and MRI. On Saturday, I had another stroke. This time I was transferred to hospital. I had a huge blood clot on the left side of my brain which has effected my speech and walking. My entire life has been effected and changed. I had a plethora of tests done, MRI, CAT SCAN, EKG, BLOOD WORK etc. I also have to have speech therapy, physical therapy and occupation therapy. I spent about weeks in the hospital. The doctors think it is a possibility that the 2 Moderna vaccine caused my two strokes. What can be done about this? I will have problems for the rest of my life.

COVID19 VACCINE	MODERNA	1105535-1	60-64 years	10-14 days	Multiple blood clots in right leg (DVT) and multiple blood clots in lungs (PE)
COVID19 VACCINE	MODERNA	1105911-1	65+ years	10-14 days	RLE DVT
COVID19 VACCINE	MODERNA	1110669-1	65+ years	10-14 days	Pulmonary embolism, asymptomatic, seen on CT angio.
COVID19 VACCINE	MODERNA	1111633-1	65+ years	10-14 days	Developed sore throat on March 3, then had negative strep test. Sore throat persisted and saw ENT with normal exam. Lost sense of smell and taste on March 7th. Negative Covid test on March 10. Developed swelling in left leg on March 9, and had ultrasound on March 10 that showed DVT. Was hospitalized on March 10 and had second negative Covid test by PCR.
COVID19 VACCINE	MODERNA	1127071-1	65+ years	10-14 days	Feb 25th afternoon I started feeling pretty yucky. As the evening progressed I had chills, body aches, and fever. I thought I had covid. On the 26th I was worse. on the 27th I went to the ER, and the diagnosis was ""unknown virus"" I continued to get worse. On March 3rd I called the nurse and she said ""I need to go to the ER, don't go to the ER, go to the closest ER to you"". I received the same diagnosis. I thought maybe my CPAP machine had bacteria and they tested for bacteria and it was negative. I went home. On march 8th I was really bad off, I had 103.7 fever still and O2 was 70-80. I was admitted to the hospital. they tested me again and I had bacterial pneumonia. 3 days later they were going to send me home but when I woke up that morning I felt like I had been kicked in the ribs on my right side. I sat in a chair and if I coughed, hiccuped or anything It felt like a knife through my chest. a CT scan showed a massive blood clot in my lung. I was put on medications and I was discharged on March 17th. My left lung had 100% pneumonia and the blood clot was in the right lung and my lungs were unable to help each other. With any exertion, my heart rate jumps and my O2 drops. I can only sit. The theory they had at the hospital is that the Moderna vaccine had the full attention of my immune system which allowed other infections to come into my body unchecked. Since the pandemic started I have left my house on my bicycle to the store and that is it. I have had almost no exposure.""
COVID19 VACCINE	MODERNA	1129076-1	65+ years	10-14 days	Dyspnea, chest pressure, fatigue. Sought care at the hospital/ED – found to have acute pulmonary emboli (by CT) with hypoxic respiratory failure. Treated with hospitalization, Xarelto, nasal canula oxygen. She improved to be stable on room air with improvement of her symptoms and went home after 3 days.
COVID19 VACCINE	MODERNA	1129691-1	65+ years	10-14 days	Deep Vein Thrombosis in both legs; eye was completely black/veins in the back of eye are completely black; eyes started to go very blurry; scared to sleep at night, scared to move/afraid to live life, petrified with this; arm is sore and puffed up; arm is sore and puffed up; A spontaneous report was received from a consumer, concerning a 72-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and developed deep vein thrombosis (DVT) in both legs/deep vein thrombosis, one clot from groin to mid chest and one behind knee to groin, quite large and very risky, extremely large thrombus, scared to sleep at night, scared to move, afraid to live life, petrified with this/ fear, eyes started to go very blurry/ vision blurred, left eye was completely black and veins in the back of eye are completely black/ eye contusion and arm was sore/ pain in extremity and puffed up/ peripheral swelling. The patient's medical history included being a cancer survivor twice. No relevant concomitant medications were reported. On 26 Feb 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 014M20A) intramuscularly in left arm for prophylaxis of COVID-19 infection. On 09 Mar 2021, approximately ten days after receiving vaccine, the patient's eyes started to go very blurry, her left eye was completely black and veins in the back of eye were completely black. On 10 Mar 2021, she had one clot from groin to mid chest and one behind knee to groin, quite large and very risky, extremely large. She was afraid to live her life and was petrified. She developed a DVT in both legs and was taken to the emergency room. She was hospitalized on 10 Mar 2021and had positron emission tomography (PET) scan, doppler, echocardiogram with pictures of face and neck. Her lung was dyed, she had 3 types of dye, had PET scan for brain, chest, blood draws from finger and shots of blood thinner in stomach. She was scared to sleep at night and scared to move. Her arm was sore and puffed up. On 13 Mar 2021, she was discharged from the hospital. Treatment of the events included Eliquis. Action taken with mRNA-1273 in response to the events was unknown. The outcome of the events, deep vein thrombosis, fear, vision blurred, eye contusion, pain in extremity and peripheral swelling were unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

COVID19 VACCINE	MODERNA	1131196-1	Unknown	10-14 days	blood clot; Vertigo; Nausea; Vomiting; A spontaneous report, was received from a consumer concerning a 53 year old female patient who received Moderna's COVID-19 Vaccine (mRNA-1273), and experienced vertigo , nausea, vomiting and also developed a blood clot (thrombosis) during hospitalization. Patient had no medical history. The concomitant medication included were zolpidem tartrate 10mg nightly, allopurinol 100mg daily, duloxetine 50mg daily, multivitamin, vitamin d and acetylsalicylic acid 81mg. On 05 Feb 2021, prior to the onset of events, the patient received the first of two planned doses of mRNA-1273 (Batch no- 010MZ0A), intramuscularly in the left upper arm for prophylaxis of COVID-19 infection. On 17 Feb 2021, few days after administering the vaccine, the consumer experienced vertigo related nausea and vomiting. The patient was hospitalized for two days and experienced a blood clot during hospitalization. Patient was treated with only diazepam on first two days of treatment. In hospital, patient was given medizine, diazepam and other anti-nausea medication whereas at home, patient was treated with ondansetron 8 mg, medizine and diazepam. On 05 Mar 2021, the patient received the second of two planned doses of mRNA-1273 (Batch no- 036A21A), intramuscularly in the left upper arm for prophylaxis of COVID-19 infection. The action taken with the second dose of mRNA-1273 in response to the event was not applicable. The outcome of the events, vertigo, nausea, vomiting was not recovered whereas the outcome of blood clot was unknown at the time of the report.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1135723-1	65+ years	10-14 days	Blood Clot in Leg; A spontaneous report was received from consumer concerning a 70-years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced blood clot in leg. The patient's medical history was not reported by the reporter. Concomitant medications taken by the patient included blood thinners for blood clot. On 21-Jan-2021, the patient received her first of two planned doses of mRNA-1273 (Lot number: 013L20A) through intramuscular route on left upper arm for prophylaxis of COVID-19 infection. On 18-Feb-2021, prior to the onset of the event, the patient received their second of two planned doses of mRNA-1273 (Lot number: 013M20A) through intramuscular route at right upper arm for prophylaxis of COVID-19 infection. On 23-Jan-2021, after the first dose patient developed leg pain. The patient reported of having the leg pain linger for about 2 weeks before seeing a healthcare professional. The healthcare professional had later found that the leg pain was related to the development of a blood clot. Relevant Treatment for the event was with blood thinner. The patient received both scheduled dose of mRNA-1273; therefore, action taken with the drug in response to the event is not applicable. The outcome of event, blood clot in leg was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1144314-1	65+ years	10-14 days	patient complained of shortness of breath of 3/22/2021 to primary care physician approximately 1 week post covid vaccine. CT Scan was ordered. Confirmed on 3/26/2021 as Left Lower lobe occlusion and diagnosed with Pulmonary embolism. On 3/26/2021 at Emergency department, he also showed bilateral PE with large clot burden. Patient is hospitalized a this point since 3/26/2021 and has been treated for PE since. He was discharged on 3/28/2021 and continue treatment as appropriate with Rivaroxaban.
COVID19 VACCINE	MODERNA	1146300-1	65+ years	10-14 days	Systemic: blood clots-Medium, Systemic: Nausea-Medium, Systemic: Neurological Disorder (diagnosed by MD)-Medium, Systemic: Stroke-Severe
COVID19 VACCINE	MODERNA	1147584-1	65+ years	10-14 days	Patient developed SOB 2/10/2021 and was diagnosed with PE/DVT at a local hospital
COVID19 VACCINE	MODERNA	1148956-1	65+ years	10-14 days	Multiple blood clots. Began in left calf then spread to multiple sites on the right side of body including pulmonary embolism.

COVID19 VACCINE	MODERNA	1153142-1	65+ years	10-14 days	bleed on her stomach; blood clot on her leg; A spontaneous report was received from a consumer concerning a 69-year-old female patient who received Moderna (mRNA-1273) vaccine and experienced blood clot on their leg/Deep vein thrombosis and bleed on their stomach/Gastric hemorrhage. The patient's medical history was not provided. No Relevant concomitant medications were reported. On 4 Feb 2021, prior to the onset of symptoms, the patient received their first of two planned doses of mRNA-1273 (Lot number: 013M20A) in the left arm for prophylaxis of COVID-19 infection. On 14 Feb 2021, the patient had a blood clot on their leg for which the patient was hospitalized. While on treatment the patient had a bleed on their stomach. The patient was in ICU for 2 weeks and another week on a regular room. The event, bleed on their stomach, was considered life-threatening. On 4 Mar 2021, the patient was sent to a rehabilitation facility and on 16 Mar 2021, the patient was sent to their home. No Treatment information was provided. Action taken with mRNA-1273 in response to the event(s) was unknown. On an unknown date, the outcome of the events, blood clot on their leg and bleed on their stomach were considered unknown.; Reporter's Comments: Very limited information regarding this event/s has been provided at this time. Critical details such as the patient's medical history, list of concomitant medications, diagnostic findings and hospitalization details are lacking. Further information has been requested.
COVID19 VACCINE	MODERNA	1153172-1	65+ years	10-14 days	Ischemic stroke; Right side of brain and blood vessels affected badly and found blood clots because of ischemic stroke; A spontaneous report was received from a consumer concerning an 89-years-old male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) experienced ischemic stroke and right side of brain and blood vessels affected badly and found blood clots because of ischemic stroke/thrombosis. The patient's medical history included hearing issue. Concomitant medication included losartan. On 24 Feb 2021, approximately 12 days prior to onset of the events, the patient received their first of two planned doses of mRNA-1273 (batch number: 001A21A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 08 Mar 2021, the patient got ischemic stroke. The patient was in hospital for 3 days and doctor put him on blood thinner. MRI (magnetic resonance imaging) of his upper body revealed his right side of brain and blood vessels affected badly and found blood clots because of ischemic stroke. Treatment for the event included blood thinner. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events ischemic stroke and right side of brain and blood vessels affected badly and found blood clots because of ischemic stroke was not reported.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1153927-1	65+ years	10-14 days	A spontaneous report was received from a consumer who is also the 77-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced blood clots in lung/pulmonary embolism. The patient's medical history was not provided. No concomitant product use was reported. On 10 Feb 2021, the patient received first of two planned doses of mRNA-1273 (Lot number: unknown) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 23 Feb 2021, the patient was admitted to hospital with blood clots in lung. Patient was put on blood thinner. On 26-Feb-2021, the patient was discharged from hospital. Treatment medication included unspecified blood thinners. Action taken with mRNA-1273 was unknown. The outcome of the event, blood clots in lung/pulmonary embolism, was reported as resolved on 26-FEB-2021.; Reporter's Comments: Very limited information regarding the events has been provided at this time and is insufficient for causality assessment. Further information has been requested.
COVID19 VACCINE	MODERNA	1161158-1	40-49 years	10-14 days	2/9/21-second Moderna vaccine 2/11/21- called doctor due to sustained illness, cough 2/20/21-lingering chest pain/tightness/shortness of breath- ER diagnosed atypical pneumonia 2/26/21- symptoms continued, ER diagnosed anxiety 3/2/21- Primary doctor ordered chest cat scan, showed bilateral pulmonary embolisms

COVID19 VACCINE	MODERNA	1166454-1	40-49 years	10-14 days	The patient is a 45 y/o male prisoner who presented 4/3/2021 with 3 days of headache, neck pain and stiffness, sensitivity to light, and nausea. He was found to have extensive dural venous sinus thrombosis causing the symptoms. He has hypothyroidism was taking levothyroxine 150 mcg daily at time of vaccination. On admission on 4/3/2021 his TSH was found to be 12 and levothyroxine dose was increased to 175 mcg on 4/4/2021. He has no prior history of thrombosis and the only family member with thrombosis is his mother who had DVTs associated with lung cancer. He has a history of prior COVID-19 infection in April of 2020 and at that time reported 3-4 days of mild symptoms and was not hospitalized or given anticoagulation. He has not had fevers, chills, or other symptoms of infection. He received his first dose of the Moderna COVID-19 vaccine at the prison on 3/23/2021 which was 9 days prior to symptom on set 12 days prior to presentation at the hospital. He reports 2-3 days of arm soreness at the injection site in his right arm, mild neck soreness, and fatigue after the injection which had resolved prior to his current symptoms starting. He currently remains hospitalized and is being treated with anticoagulation.
COVID19 VACCINE	MODERNA	1168994-1	65+ years	10-14 days	Pulmonary embolism; Spitting out blood clots; Labored breathing; Diarrhea; Body aches; Joint aches; Fever; Exhausted; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Pulmonary embolism) in a 71-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 030M20A) for COVID-19 immunisation. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse reaction (No medical history reported.). Concomitant products included METOPROLOL and LOVASTATIN. On 13-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Feb-2021, the patient experienced OXYGEN SATURATION DECREASED (Oxygen levels have gone as low as 76 and several in the 80's), HEART RATE INCREASED (Heart rate is normally around 60, and has been in the 90's several times), PAIN (Body aches), ARTHRALGIA (Joint aches), PYREXIA (Fever) and FATIGUE (Exhausted). On 07-Mar-2021, the patient experienced DIARRHOEA (Diarrhea). On an unknown date, the patient experienced PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criterion medically significant), HAEMOPTYSIS (Spitting out blood clots), DYSPNOEA (Labored breathing) and VITAL CAPACITY ABNORMAL (Vitals are waked out). At the time of the report, PULMONARY EMBOLISM (Pulmonary embolism), HAEMOPTYSIS (Spitting out blood clots), DYSPNOEA (Labored breathing), OXYGEN SATURATION DECREASED (Oxygen levels have gone as low as 76 and several in the 80's), HEART RATE INCREASED (Heart rate is normally around 60, and has been in the 90's several times), VITAL CAPACITY ABNORMAL (Vitals are waked out), DIARRHOEA (Diarrhea), PAIN (Body aches), ARTHRALGIA (Joint aches), PYREXIA (Fever) and FATIGUE (Exhausted) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In February 2021, Body temperature: 103.7 (High) 103.7. In February 2021, Heart rate: 90s (abnormal) In the 90s several times. In February 2021, Oxygen saturation decreased: 76s (Low) has gone as low as 76 and in 80s. In February 2021, SARS-CoV-2 test negative: Negative and Negative. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment information was not provided.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1182095-1	65+ years	10-14 days	received 2nd Moderna vaccine 3/22/21 After receiving this vaccine pt started noticing dyspnea wjen walking Came to see Dr 4/1/21- was admitted to hospital with Lg bilateral pulmonary emboli thought secondary to 2nd dose of Moderna COVID vaccine,
COVID19 VACCINE	MODERNA	1187825-1	65+ years	10-14 days	blood clot in superior mesenteric vein found with Abd CT scan placed on lovenox then xarelto with relief of sxs - abd pain

COVID19 VACCINE	MODERNA	1189636-1	65+ years	10-14 days	Blood clot in leg; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (Blood clot in leg) in an 81-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 039KZ014) for COVID-19 vaccination. The patient's past medical history included No adverse reaction (No reported medical history.). On 02-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Jan-2021, the patient experienced THROMBOSIS (Blood clot in leg) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Blood clot in leg) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment information was not provided. Company Comment Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1192235-1	40-49 years	10-14 days	New onset DVT/PE blood clots. Diagnosed after patient had new onset right calf pain and cramping about 9 days after receiving second Moderna COVID vaccine, came to hospital had an ultrasound which showed clot, then had CTA chest which confirmed pulmonary embolism (both done on 4/7/2021). She has no other known risk factors for thromboembolism, however a hypercoagulability work-up is also underway and will not be completed for several months.
COVID19 VACCINE	MODERNA	1194903-1	65+ years	10-14 days	PE while on coumadin
COVID19 VACCINE	MODERNA	1198895-1	50-59 years	10-14 days	I was given my first Covid vaccine on 3/6/21. About 12 days later I started having some difficulty breathing, pounding heart and some dizziness. My symptoms got worse one the next week and a half. I went to an emergency room on 3/28/21 and was admitted to an ICU with a Saddle Embolus of Pulmonary Artery with Acute Cor Pulmonale. Many blood clots in my lungs and one very large one in the artery between my heart and lungs. I am now on Blood Thinners.
COVID19 VACCINE	MODERNA	1201362-1	30-39 years	10-14 days	Developed DVT
COVID19 VACCINE	MODERNA	1201955-1	60-64 years	10-14 days	Shortness of breath , extreme pain 3 hospital visits until blood clot was detected,now on blood thinner Eliquis
COVID19 VACCINE	MODERNA	1202257-1	40-49 years	10-14 days	Brother called pharmacy on 04.13.2021 at approximately 10am and informed pharmacist that his sister had passed away due to a pulmonary embolism about 2 weeks after receiving her first dose of the Moderna COVID vaccination at our pharmacy. He mentioned that healthcare provider was looking at possible gene mutation in family that may have contributed.
COVID19 VACCINE	MODERNA	1202602-1	65+ years	10-14 days	Bilateral pulmonary emboli and bilateral deep venous thrombosis
COVID19 VACCINE	MODERNA	1202749-1	65+ years	10-14 days	Pt was seen by me for full arm thrombosis and CNS thrombosis which occurred approximately 1 week following second vaccine
COVID19 VACCINE	MODERNA	1204121-1	65+ years	10-14 days	Noticed shortness of breath, extreme trouble breathing that worsened over 3 days. Cat scan was performed at hospital finding blood clots on lungs. Surgery was performed to eliminate the blood clots.
COVID19 VACCINE	MODERNA	1205036-1	65+ years	10-14 days	On March 30th started with headaches then progressed to shortness of breath while moving. Then on April 4th transport to hospital via EMT was tested for Covid 19 results was negative. It was determined that blood clots were found in Right leg & Left leg and both lungs and now blood clot was found in heart. PT has low platelets, low blood pressure. While in the hospital pt was given herapin . Patient has remained in ICU since the 4th to present time.
COVID19 VACCINE	MODERNA	1205454-1	40-49 years	10-14 days	Diagnosed with DVT and multiple PEs
COVID19 VACCINE	MODERNA	1205873-1	65+ years	10-14 days	right leg pain starting 1-2 weeks after first Moderna COVID vaccine (admin 2/24/21). 2-3 days after second COVID vaccine (admin 3/24/21) right leg pain intensified and was followed by right pleuritic chest pain On 3/29/21 ultrasound showed right superficial femoral DVT. CTA showed bilateral pulmonary emboli
COVID19 VACCINE	MODERNA	1208253-1	65+ years	10-14 days	He suddenly suffered a severe stroke/blood clot in brain on January 19, 2021 which was 12 days after he received his first dose of the Moderna vaccine. He went via ambulance to hospital and was inpatient there at Hospital for 2 nights.
COVID19 VACCINE	MODERNA	1209441-1	65+ years	10-14 days	My mother and I received the Moderna vaccine on January 20th. About two weeks later on January 31st, she complained about her leg. It was swollen. Later on that day, she collapsed, was rushed to the hospital. Died on February 4th due to anoxic brain injury due to DVT that caused a massive pulmonary embolism.
COVID19 VACCINE	MODERNA	1209527-1	18-29 years	10-14 days	Blood clot in left leg

COVID19 VACCINE	MODERNA	1210261-1	50-59 years	10-14 days	patient admitted to hospital with blood clot on 4.8.21
COVID19 VACCINE	MODERNA	1211262-1	50-59 years	10-14 days	Patient had her 2nd dose of Moderna COVID vaccine on 3/29. Starting 4/8, she was having shortness of breath on exertion with a mild cough. On 4/11, her husband states that he saw her sitting down watching TV, then he heard a thud in the next room and went in to see her on the floor and she started crying for help which led to him calling the paramedics. The paramedics noticed the patient was in PEA and resuscitated her and brought her to the ER. The patient appeared to have an NSTEMI and she was diagnosed with a pulmonary embolism that led to the cardiac arrest event. Patient was taken to cath lab and was found to have normal coronary arteries with no evidence of coronary artery disease. Patient was also in sepsis and had an extensive bilateral pneumonia. Patient is currently inpatient and intubated.
COVID19 VACCINE	MODERNA	1213389-1	65+ years	10-14 days	Pulmonary embolus. seen in ED and started on anticoagulation on 3/11/2021. Admitted to hospital 3/25 through 3/30 due to pericardial effusion
COVID19 VACCINE	MODERNA	1214327-1	40-49 years	10-14 days	Patient began experiencing pain in his right leg on 4/5, sought treatment at walk-in clinic on 4/12. Healthcare provider he saw sent him to ultrasound at a medical center, who then referred him to the emergency department. Patient was diagnosed with a DVT and prescribed Eliquis 10 mg BID x7 days then 5 mg BID for 6 months.
COVID19 VACCINE	MODERNA	1214582-1	65+ years	10-14 days	Patient received Moderna vaccine initial dose at clinic on 4/2/21. Patient presented to the Emergency Department on 4/14/21 with complaints of dizziness and mild nausea. CT angio chest w& w/out contrast identified pulmonary embolus within the intermediate pulmonary arteries bilaterally. Treatment started 4/14/21 with Eliquis (apixaban) patient admitted for observation overnight and discharged in stable condition on 4/15/21.
COVID19 VACCINE	MODERNA	1214884-1	65+ years	10-14 days	1. Bilateral acute pulmonary emboli noted. No evidence of right ventricular strain. 2. Prominence of the pulmonary interstitium and ground-glass density throughout both lungs. This is suggestive of bilateral pulmonary edema. Bilateral pneumonia can give a similar appearance. 3. Small bilateral pleural effusions, right larger than left.
COVID19 VACCINE	MODERNA	1214952-1	50-59 years	10-14 days	10 days after 1st shot. Blood clot traveled to right lung. Placed on blood thinners, and pain meds, follow up treatment scheduled for mid May. Unknown reason for blood clot. No prior injuries or surgery.
COVID19 VACCINE	MODERNA	1215882-1	50-59 years	10-14 days	fatal pulmonary embolism from RLE DVT
COVID19 VACCINE	MODERNA	1216712-1	65+ years	10-14 days	Patient received second Modern COVID vaccine on 3/13. On 3/27 she developed shortness of breath. She presented to her local ED and was found to have a large saddle pulmonary embolism. She underwent thrombectomy with IR x2 and was transferred to Medical Center for surgical pulmonary thromboendarterectomy.
COVID19 VACCINE	MODERNA	1217056-1	65+ years	10-14 days	Acute pulmonary embolism, first symptomatic on the evening of 4/15/21. Received first vaccine on 3/5/21, second vaccine on 4/2/21. Only other risk factors for PE are age and a long car trip around 3/14/21.
COVID19 VACCINE	MODERNA	1218158-1	60-64 years	10-14 days	On 4/7/2021 I was hospitalized with a heart attack due to an embolism in my LAD. Had to be re-stented. In ICU for 5 days- regular hospital 2 and discharged after total of 7 days
COVID19 VACCINE	MODERNA	1219160-1	65+ years	10-14 days	Felt fine after vaccination. Estimating that around February 15th is when he began not feeling well. Stated he had abdominal pain and a general feeling of unwellness. He went to medical center on February 22nd and was then transferred to medical center. Patient stated that several tests were ran and he had blood clots in his heart and spleen. Upon further scans and testing including a heart catheterization nothing could be found as the cause for the clots. Patient had not had history of clots before. Permanent damage to the heart and spleen.
COVID19 VACCINE	MODERNA	1223371-1	65+ years	10-14 days	Patients First dose 01/13/2021 and second dose of Moderna Covid 19 vaccine was administered on February 11th. Patient developed pulmonary embolism in both lungs and hospitalized February 25th. Patient later developed PCP Pneumonia and died March 23rd.
COVID19 VACCINE	MODERNA	1270128-1	65+ years	10-14 days	Patient developed 2 DVT in right leg on 4/5/2021. Patient was seen at Hospital for event, but was not hospitalized. Patient was placed on Eliquis for DVT and sent home. Patient states that he continues on Eliquis and that the swelling in his right leg is going down. Patient noted that he did take a long drive the day before, but has done this many times and never had this problem before. Patient received both Moderna vaccines listed. Dose 1, 2/21/2021 and Dose 2, 3/24/2021. Stated that he has not had any other vaccines in the past several months.

COVID19 VACCINE	MODERNA	1276749-1	Unknown	10-14 days	<p>Blood clots in the legs and lungs; he passed out and still currently admitted in hospital; Blood clots in the legs and lungs; 2nd dose given 2 weeks from the 1st dose; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Blood clots in the legs and lungs), LOSS OF CONSCIOUSNESS (he passed out and still currently admitted in hospital) and DEEP VEIN THROMBOSIS (Blood clots in the legs and lungs) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 05-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 19-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 19-Mar-2021, the patient experienced PRODUCT ADMINISTRATION ERROR (2nd dose given 2 weeks from the 1st dose). On 22-Apr-2021, the patient experienced PULMONARY EMBOLISM (Blood clots in the legs and lungs) (seriousness criteria hospitalization and medically significant), LOSS OF CONSCIOUSNESS (he passed out and still currently admitted in hospital) (seriousness criteria hospitalization and medically significant) and DEEP VEIN THROMBOSIS (Blood clots in the legs and lungs) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on 22-Apr-2021 due to DEEP VEIN THROMBOSIS, LOSS OF CONSCIOUSNESS and PULMONARY EMBOLISM. On 19-Mar-2021, PRODUCT ADMINISTRATION ERROR (2nd dose given 2 weeks from the 1st dose) had resolved. On 22-Apr-2021, LOSS OF CONSCIOUSNESS (he passed out and still currently admitted in hospital) had resolved. At the time of the report, PULMONARY EMBOLISM (Blood clots in the legs and lungs) and DEEP VEIN THROMBOSIS (Blood clots in the legs and lungs) outcome was unknown. Not Provided For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was reported by the reporter. Patient reported that he had diagnosed to have blood clots in the leg and lungs and had unspecified procedure. Patient reported that he was given a unknown medication.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, the reported drug administration error (2nd dose administered 2 weeks from 1st dose) may remain a confounder.</p>
COVID19 VACCINE	MODERNA	1290096-1	50-59 years	10-14 days	<p>4/20/21: patient arrived to ER per EMS status post PEA arrest. Per ER records, patient became unresponsive while sitting in bed witnessed by husband at home. According to husband, they had come home, she sat on the bed and complained she was not feeling good. She then fell back on the bed and began to seize. Subsequently she had intermittent episodes of alertness and was able to speak to the husband followed by unresponsiveness. At time of EMS arrival pt. was unresponsive. EMS noted BS 120s, SBP 50s. En route to hospital, pt. had a CP arrest for which epinephrine was given, CPR initiated with ROSC. Pt. arrived to the ER on a NRB mask attempting to speak. Subsequently, pt. had several CP arrests with asystole, and</p>
COVID19 VACCINE	MODERNA	1294370-1	65+ years	10-14 days	<p>Patient received the COVID-19 vaccine on Thursday, March 25, 2021. On Tuesday April 6, 2021 he had a massive stroke, blood clot to left side of his brain. On Friday morning April 9, 2021 doctor's advised he had another stroke due to bleeding in the brain (paralysis on right side and racing heart beat). He died on Saturday, April 10, 2021 @ 5:45 AM.</p>

COVID19 VACCINE	PFIZER\BIONTECH	0934912-1	18-29 years	10-14 days	DVT; have pain in same site where DVT is; This is a spontaneous report from a contactable consumer. A 28-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EK9291), via an unspecified route of administration in left deltoid on 24Dec2020 10:00 at first single dose for COVID-19 immunization. Medical history was none. There were no concomitant medications. Caller was calling to report a possible adverse reaction to the Pfizer Covid-19 vaccine. The patient was currently at hospital, she was admitted for deep vein thrombosis (DVT) of left iliac vein, the patient had no past history as to why this would happen, that she is only 28 years old. Received the vaccine on 24Dec2020, the following day she did have pain in same site where DVT was. Took ibuprofen for the pain. The patient was admitted yesterday 04Jan2020 for the DVT, they were currently treating her with Lovenox injections and prescribing dose for discharge is Eliquis. CT scans and three shots of Lovenox for it, doing a doppler of bilateral legs and echocardiogram (echo) of her heart to make sure there is nothing else. The AEs require a visit to emergency room. The patient was asking if she can still get the 2nd dose based off the adverse event she experienced. Outcome of DVT was not recovered, of pain was unknown.
COVID19 VACCINE	PFIZER\BIONTECH	0945011-1	60-64 years	10-14 days	Developed DVT in left leg around January 9. Developed pain, redness and swelling in left calf
COVID19 VACCINE	PFIZER\BIONTECH	0959549-1	50-59 years	10-14 days	1/4/21- Patient stated she had tenderness on the back of her left lower leg with redness then 1/8/21 started to have shortness of breath and made a doctor's appointment for 1/13/21. Seen by provider on 1/13/21 and was sent to ED and admitted to the hospital [ICU] with NSTEMI, acute deep, occlusive venous thrombosis left femoral vein and saddle embolus of pulmonary artery. Transferred to another acute care hospital for removal of thrombosis. Patient started on Eliquis and no intervention for removal of the thrombosis.
COVID19 VACCINE	PFIZER\BIONTECH	0974922-1	30-39 years	10-14 days	Pulmonary embolism.
COVID19 VACCINE	PFIZER\BIONTECH	0979379-1	60-64 years	10-14 days	19th vaccinated; my wife was exposed to COVID on 26th and she developed symptoms on 29th; I developed on 31st and tested Positive on January 2 for COVID; January3, I was admitted to ER for shortness of breath, my oxygen saturation - between 88 and 94; I was in the hospital and discharged on January 8. Remdesivir and Decadron treated with and also Eliquis. I was on oxygen until Wednesday (three days) and then I went home on 8th and continued on Prednisone for last week (Friday). Haven't gone back to work - shortness of breath, fatigue and headaches continue.
COVID19 VACCINE	PFIZER\BIONTECH	1009384-1	18-29 years	10-14 days	Tingling beginning at thumb and pointer finger, progress to forearm and upper arm over 3 days. Swelling began near elbow, redness and pain followed and immobility. Visited ER on 2/3/21 and diagnosed with superficial thrombophlebitis
COVID19 VACCINE	PFIZER\BIONTECH	1017129-1	65+ years	10-14 days	Sudden cardiac death. Autopsy report: right coronary artery thrombosis.
COVID19 VACCINE	PFIZER\BIONTECH	1024662-1	50-59 years	10-14 days	On January 8, I started having a cramping feeling in my right calf. It went on throughout the day without a event. I woke up the next morning, and the crap was worse. I ran some errands and came home and then looked at my calf of my leg and it was twice the size as my other leg. I had four spots of bruising from ankle to knee. I immediately went to the emergency room. I was hospitalized and had bloodwork and an MRI done which showed that I had a DVT and a pulmonary embolus in my right lung. I was hospitalized for two days on blood thinners. I had no shortness of breath or heart problems during this time. I was then released from the hospital on blood thinners which I have to take for the next six months.
COVID19 VACCINE	PFIZER\BIONTECH	1038473-1	65+ years	10-14 days	1 week after receiving first dose of Pfizer COVID vaccine (received 1/26/2021), develop worsening shortness of breath. Presented to ER on 2/4/2021. Found to have submassive pulmonary embolism with evidence of right heart strain, US showed left lower extremity DVT. Also found to have descending aortic thrombus with extensive clot burden. Was hypoxic 89% on room air.
COVID19 VACCINE	PFIZER\BIONTECH	1050154-1	65+ years	10-14 days	Pulmonary Embolism right lung and blood clot in right leg. No travel or other events or activities are known that might have contributed to blood clots in leg and lung. Symtoms of embolism first appeared about 10 days following 2nd dose of Pfizer vaccine.
COVID19 VACCINE	PFIZER\BIONTECH	1052023-1	65+ years	10-14 days	large lower extremity deep venous thrombosis and small pulmonary embolus; outcome: responded well to anti-coagulants, with decreased pain, swelling and improved oxygenation

COVID19 VACCINE	PFIZER\BIONTECH	1052373-1	30-39 years	10-14 days	Blood clot on lung after experiencing chest pain; This is a spontaneous report from a contactable consumer reported for himself. A 38-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 23Jan2021 14:00 on Arm left at single dose (Lot # EK9231) for covid-19 immunisation. Prior to vaccination, was the patient did not diagnose with COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient with confirmed blood clot on lung after experiencing chest pain/chest tightness/left sided, thought that he was having a heart attack, shortness of breath on 03Feb2021, reported as non serious. Emergency room/department or urgent care. Blood thinner received for the events. Outcome of the events was unknown.
COVID19 VACCINE	PFIZER\BIONTECH	1054591-1	40-49 years	10-14 days	Stroke on January 20th, 2021. Unknown cause for blood clot.
COVID19 VACCINE	PFIZER\BIONTECH	1066342-1	30-39 years	10-14 days	I ended my normally scheduled menstrual cycle on 02/06/2021, and exactly 6 days later (02/15/2021) I had severe menstrual bleeding with blood clots that has continued to this day (03/02/2021). I went to urgent care and was prescribed Provera to stop the bleeding to no avail. I then proceeded to go to urgent care again because the bleeding had not stopped. At my second Doctors visit, I had an abdominal and a transvaginal ultrasound done, and both of them came back completely normal. I have now scheduled an upcoming obgyn appointment, but cannot be seen until 03/09/2021.
COVID19 VACCINE	PFIZER\BIONTECH	1070629-1	50-59 years	10-14 days	51 y/o female, no chronic health problems. 14 days following first COVID Pfizer vaccine, I felt unable to take a deep breath, on day 15 following the vaccine, I became short of breath,; on day 16 I was having mild chest pain with inspiration and shortness of breath; day 17 following vaccination I became significantly short of breath, with moderate to severe chest pain with inspiration and tachycardia (heart rate in the 140's). I called my PCP who ordered an EKG, CXR, COVID swab, a metabolic panel, a CBC, and a D-dimer. My D-dimer was elevated and he called me to go directly to the emergency department, which I did and had a CTA chest. I was diagnosed with multifocal pulmonary emboli in my right lung with a slight pleural effusion on my left lung. I had a duplex ultrasound of my legs which was negative for DVT, and an echocardiogram which was within normal limits. I was finally diagnosed with acute unprovoked pulmonary embolism, given a Heparin bolus and started on a Heparin IV infusion. Ultimately, I transitioned to Eliquis PO and was discharged from the hospital within 24 hours.
COVID19 VACCINE	PFIZER\BIONTECH	1074532-1	65+ years	10-14 days	Patient fractured his hip and 2/22, underwent hip surgery, discharged to but readmitted with R lower DVT and bilateral pulmonary emboli.. Treated with IV heparin. Per EAU, hospitalizations are to be reported irrespective of attribution to the vaccine.
COVID19 VACCINE	PFIZER\BIONTECH	1077988-1	30-39 years	10-14 days	# AKI with non-nephrotic range proteinuria and microscopic hematuria # Neutrophilia # Fevers # Normocytic anemia # Thrombocytosis # Coagulopathy # RUE Superficial venous thrombosis # Subconjunctival hemorrhage # Flame hemorrhage R fundus # Mild iridocyclitis # CRP elevation # Procalcitonin elevation # D Dimer elevation # Anasarca # Elevated BNP # Hypoalbuminemia # Small pericardial effusion # Elevated alk phos, bilirubin (direct predominant), and AST # Elevated lipase # Hypocomplementemia with low CH50 # Elevated IL2 Receptor (8540) # Aseptic meningitis w CSF with lymphohistiocytic predominant pleocytosis (25 nuc cells with 49% lymphs, 35% histiocytes, 16% pmn, glucose 41, protein 155 with neg meningoencephalitis panel)
COVID19 VACCINE	PFIZER\BIONTECH	1079837-1	65+ years	10-14 days	Severe shortness of breath, and decrease in oxygen saturation to 61%, 2 weeks after second Covid Vaccine dose. He was rushed to the hospital and was diagnosed with pulmonary embolism and received oxygen therapy. He also received Lovenox injections and then apixaban orally.
COVID19 VACCINE	PFIZER\BIONTECH	1094049-1	65+ years	10-14 days	dvt left leg treated without sequelae
COVID19 VACCINE	PFIZER\BIONTECH	1096940-1	65+ years	10-14 days	lost total vision in left eye, took about 2 seconds from onset. Recovered within 30 minutes. Suspect small clot. No other symptoms. No detectable lasting vision impact.
COVID19 VACCINE	PFIZER\BIONTECH	1098030-1	40-49 years	10-14 days	Woke up with sore upper right thigh Tuesday March 9. Very tender to the touch. Visited Dr. Wednesday March 10, ordered ultrasound which was completed on Thursday March 11 and diagnosed a superficial blood clot. Prescribed Xarelto 10mg.
COVID19 VACCINE	PFIZER\BIONTECH	1098756-1	65+ years	10-14 days	Patient has rt lower lobe Pulmonary emboli and rt popliteal dvt
COVID19 VACCINE	PFIZER\BIONTECH	1111554-1	65+ years	10-14 days	Multiple strokes resulting from blood clots starting 10 days past 2nd shot. Fuzzy headed with headache prior to strokes.
COVID19 VACCINE	PFIZER\BIONTECH	1111680-1	65+ years	10-14 days	Developed severe back pain. which she went to the ER to have evaluated. Upon evaluation, she was diagnosed with a PE and blood clots in her spleen

COVID19 VACCINE	PFIZER\BIONTECH	1114381-1	65+ years	10-14 days	Pulmonary Embolism; This is a spontaneous report from a contactable consumer (patient). A non-pregnant 84-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration (Lot Number: EL9261) at 9:00 am on 22Jan2021 (at 84-year-old) in arm right at single dose for COVID-19 immunization. Other medical history was reported as high blood pressure (HBP), high cholesterol, thyroid cancer removed in 2003 (thyroid cancer from an unspecified date to 2013), breast cancer from 2009, hemorrhoid surgery in 2011, polymyalgia rheumatica (2018 & 2020), hip injections in 2018 & 2020, and cataracts removed both eyes in 2018 (cataracts from an unspecified date to 2018). The patient had allergy to morphine. Concomitant medications (other medications in two weeks) included levothyroxine sodium (SYNTHROID), metoprolol, triamterene, montelukast, and atorvastatin calcium (ATOR), all taken for an unspecified indication, start and stop date were not reported. There's no other vaccine in four weeks. The patient experienced pulmonary embolism at 02:00 am on 01Feb2021. The event resulted in emergency room/department or urgent care, hospitalization for 3 days, life threatening illness (immediate risk of death from the event). The event treatment included apixaban (ELIQUIS). The patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EM9809) via an unspecified route of administration at 9:00 am on 12Feb2021 in arm right at single dose for COVID-19 immunization. No COVID prior vaccination, and no COVID tested post vaccination. The outcome of the event was unknown.
COVID19 VACCINE	PFIZER\BIONTECH	1115731-1	65+ years	10-14 days	Large bilateral pulmonary embolus
COVID19 VACCINE	PFIZER\BIONTECH	1118591-1	Unknown	10-14 days	Hospitalized March 6th 2021. Numbness, loss of use left foot, leg, L-ARM, HAND. DAZED, COULDN'T CONCENTRATE, FUNCTION. TAKE TO EMERGENCY ROOM at Piedmont Athens Reg Med Ctr and admitted. Had cat scans, MRI's, ultrasounds, EKG's. Blood clots etiology unknown, caused by COVID 19 VACCINES. PFIZER
COVID19 VACCINE	PFIZER\BIONTECH	1119208-1	50-59 years	10-14 days	10 days after my second shot of the Covid vaccine, I was short of breath and my heart rate was elevated. I went to the hospital and they found blood clots in both lungs and I had to be hospitalized.
COVID19 VACCINE	PFIZER\BIONTECH	1121607-1	65+ years	10-14 days	she was hospitalized with pulmonary embolism and they also found blood clots in her spleen (she had both venous and arterial clots).; she was hospitalized with pulmonary embolism and they also found blood clots in her spleen (she had both venous and arterial clots).; she was hospitalized with pulmonary embolism and they also found blood clots in her spleen (she had both venous and arterial clots).; This is a spontaneous report from a contactable Nurse. A 72-year-old female patient (Reporter's mother, not pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 27Jan2021 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunization. Medical history included hypertension (HTN), hyperlipidemia and high cholesterol. The patient's concomitant medications were not reported. No other vaccine in four weeks. 2 weeks after the immunization, 06Feb2021 the patient was hospitalized with pulmonary embolism and they also found blood clots in her spleen (she had both venous and arterial clots). Follow up with hematologist after discharge, MD reported unable to determine cause of clots. AE resulted in Emergency room/department or urgent care, Hospitalization. The patient hospitalized for three days. The patient received treatment blood thinners. The patient tested Covid post vaccination on 06Feb2021 with negative result. The outcome was Recovered with Sequel. Information on the lot/batch number has been requested.; Sender's Comments: The causal relationship between BNT162B2 and the reported events cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.

COVID19 VACCINE	PFIZER\BIONTECH	1122743-1	40-49 years	10-14 days	<p>severe thrombocytopenia; Bleeding at Impella insertion site; peripheral swelling in hands/feet; cardiogenic shock; myocarditis; hypoxic respiratory failure; mural thrombus; hypotensive despite pressors; fever; cough; myalgias; This is a spontaneous report from a contactable physician. A 46-year-old non-pregnant female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Lot number and Expiration date was not provided), intramuscularly on 05Feb2021 as a single dose for COVID-19 immunisation. The patient's medical history included hyperlipidemia and COVID-19 pneumonia from an unspecified date in Jan2021 to an unspecified date in Jan2021 (the patient was diagnosed with COVID-19 pneumonia prior to the vaccination. Recovered. Returned to work on 25Jan2021). Concomitant medications included atorvastatin orally at 10 mg, once a day, acetylsalicylic acid (ASPIRIN) orally at 81 mg, once a day, colesticalferol (VITAMIN D); all the drugs were received within two weeks. The patient previously took clindamycin and experienced known allergies: Clindamycin. The patient did not receive other vaccine in four weeks. The patient developed fever, cough, myalgias on 19Feb2021 at 12:00 AM. She developed peripheral swelling in hands/feet on 24Feb2021, she was evaluated in the ER; admitted to (hospital name withheld) on 24Feb2021 with cardiogenic shock, myocarditis, hypoxic respiratory failure. The patient was started on IV vancomycin and Unasyn. TTE (transthoracic echocardiogram) demonstrated LVEF (left ventricular ejection fraction) 35%; reduced biventricular function; mural thrombus on 24Feb2021. Remained hypotensive despite pressors on 24Feb2021. Patient had elevated PCW with preserved cardiac index. Patient underwent VA ECMO (veno-arterial extracorporeal membrane oxygenation) and Impella placement on 25Feb2021. COVID-19 PCR was negative. Blood cultures were no growth. She developed severe thrombocytopenia and developed bleeding at Impella insertion site on 25Feb2021; required multiple, PRBC transfusions. Evaluated for HLH; Soluble IL2 receptor on 26Feb2021 elevated at 7232 pg/mL; ferritin 3054; CRP &gt; 300. ECMO stopped 03Mar2021. The patient was treated with IV antibiotics, mechanical ventilation, pressor support, underwent VA ECMO and Impella placement. The patient was hospitalized from 24Feb2021 to 16Mar2021. Number of days of hospitalization was 20 days. The patient tested COVID post vaccination. The patient underwent lab tests and procedures which included blood pressure: hypotensive despite pressors, LVEF: 35 %, nasal swab: Negative on 24Feb2021, blood cultures: No growth, nasal swab: Negative on 25Feb2021, ferritin: 3054, HLH: Evaluated, Soluble IL2 receptor: 7232 pg/mL (elevated at 7232 pg/mL), CRP: &gt; 300 on 26Feb2021, nasal swab: Negative on 11Mar2021, nasal swab: Negative on 14Mar2021. The events were considered as serious (hospitalization and life threatening) by the physician. The outcome of the events was recovering. Information about lot/batch number has been requested.; Sender's Comments: the events being serious, life threatening and hospitalisation ,medical intervention required are assessed as possibly related to the suspect drug __BNT162B2__ based on strong temporal association, but consider also possible contributory effects from patient's medical history and/or concomitant medications.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1135488-1	65+ years	10-14 days	<p>blood clots right nostril; pain/discomfort right side at waistline going toward back; pain/discomfort right side at waistline going toward back; This is a spontaneous report from a contactable consumer (patient). An 82-year-old female patient received the 2nd dose of bnt162b2 (BNT162B2, Lot Number: EL9581), as single dose in left arm on 06Feb2021 10:30 for COVID-19 immunisation, administered at hospital. Medical history included artificial mitral valve. No known allergies. The patient was not pregnant. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient received concomitant medications in two weeks but were not reported. No other vaccine in four weeks. The patient received the 1st dose of bnt162b2 (BNT162B2), on an unknown date for COVID-19 immunisation and experienced pulsatile tinnitus right ear. The patient experienced blood clots right nostril, pain/discomfort right side at waistline going toward back on 16Feb2021. The patient was hospitalized for blood clots right nostril. She went to Dr. for tinnitus, had MRI and CAT scan in 2021. All tests were negative. She received no treatment. COVID was not tested post vaccination. Right side got better after several days in 2021. Blood clots in nose lasted one morning and recovered on 06Feb2021.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1135820-1	65+ years	10-14 days	<p>Shortness of breathe and PE . Hospitalized 3 days</p>

COVID19 VACCINE	PFIZER\BIONTECH	1143491-1	50-59 years	10-14 days	heavy bleeding with lots of blood clots; extended and heavy menstrual period/ heavy bleeding with lots of blood clots; This is a spontaneous report from a contactable consumer (patient). A 51-year-old non-pregnant female patient received second dose of BNT162B2 (Pfizer product), lot no. EN5318, via an unspecified route of administration (left arm) on 19Feb2021 at a single dose for COVID-19 immunisation at a workplace clinic. Medical history included high cholesterol and anxiety. No known allergies. No COVID prior to vaccination. Concomitant medications were not reported. Historical vaccine included first dose of BNT162B2 (brand: Pfizer, lot no. EL9261, left arm) for COVID-19 immunisation on 30Jan2021 at age of 50 years old. No other vaccine in four weeks. The patient was experiencing extended and heavy menstrual period. Her cycle began on 05Mar2021 and was still happening as of today 16Mar2021. She had heavy bleeding with lots of blood clots. This was not normal for her at all. She is calling her doctor tomorrow. No treatment received for the events. No COVID test post vaccination. The outcome of the events was not recovered.
COVID19 VACCINE	PFIZER\BIONTECH	1143958-1	50-59 years	10-14 days	DVT of left lower extremity 2 weeks after first shot PE
COVID19 VACCINE	PFIZER\BIONTECH	1148785-1	65+ years	10-14 days	Chills; seems to have some kind of hypothermia/kept reading 94.7; hemorrhoids; pulmonary embolism in his right lower lobe; This is a spontaneous report from a contactable pharmacist (patient). A 68-year-old male patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration on 03Mar2021 (Batch/Lot Number: EN6198; Expiration Date: 30Jun2021), at the age of 68-years at vaccination, as SINGLE DOSE for COVID-19 immunisation. Medical history included paraplegic, he has been paralyzed for 45 years. The patient received first dose of the vaccine on 10Feb2021 with lot number: EN5318, expiration 31May2021. There were no concomitant medications. The patient went on Monday to the ER for an unrelated condition and they did a CT scan and found a blood clot, a pulmonary embolism in his right lower lobe. He confirms the pulmonary embolism was diagnosed on Monday, 15Mar2021. He got home that night and read the headline in the (Withheld) times that said several European countries are pulling the Astra Zeneca vaccine over concerns about blood clots even though there has not been any causal relationship found. He thought that with the drug companies, they should be able to have data regarding potential adverse effects for Pfizer so he was calling report that. He discusses it with the ER doctor and he couldn't really figure out why he had a blood clot, it was incidental to what he was being scanned for, it surprised him. They put him on Eliquis so he is on an anticoagulant, which will cost him a fortune. Today will be the third day he has been on the Eliquis. He is at home and he would say his only concern is that he does have hemorrhoids so when he has bowel movement tomorrow, because he doesn't go every day, but when he goes he is concerned if he starts to bleed that the anti-coagulant might cause the bleeding to be more significant than it usually is. No further information provided. His only other concern is he seems to have some kind of hypothermia, he is not entirely sure because of his thermometer is not very good. That is the reason he went into the Emergency Department because it kept reading 94.7 and he googled it and it said if it is below 95 it is a medical emergency and go to the ER so he got to the Emergency Department and it was 97.6 and now he checked his temperature again with the thermometer and it was 96.8 so either he has a faulty thermometer or something but he is experiencing some kind of chills. The outcome of the events was unknown.

COVID19 VACCINE	PFIZER\BIONTECH	1162082-1	65+ years	10-14 days	developed blood clots in my left leg that began swelling some on 12Mar2021 and by Monday 15Mar2021 it was huge and 16Mar2021 big and hurting; developed blood clots in my left leg that began swelling some on 12Mar2021 and by Monday 15Mar2021 it was huge and 16Mar2021 big and hurting; developed blood clots in my left leg that began swelling some on 12Mar2021 and by Monday 15Mar2021 it was huge and 16Mar2021 big and hurting; This is a spontaneous report from a contactable consumer (patient). A 71-year-old male patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/Lot Number: EN6202), via an unspecified route of administration, administered in Arm Left on 02Mar2021 16:00 (at 71-year-old) as single dose for COVID-19 immunization. Medical history included Arthritis in knee. High blood pressure. Patient had no covid prior vaccination and no covid tested post vaccination. Patient has no known allergies. Concomitant medication included hydrochlorothiazide. The patient previously took first dose of BNT162B2 for COVID-19 immunization. The patient developed blood clots in my left leg that began swelling some on 12Mar2021 17:00 and by Monday 15Mar2021 it was huge and 16Mar2021 big and hurting. So he went to urgent care and they sent him to hospital ER. The patient was hospitalized for 3 days. Events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization. Events treatment included Ultra sound, CT scan, heparin blood thinner. The outcome of the events was not recovered.
COVID19 VACCINE	PFIZER\BIONTECH	1163369-1	65+ years	10-14 days	Blood clots
COVID19 VACCINE	PFIZER\BIONTECH	1167520-1	60-64 years	10-14 days	Pt presented to the ER on 3/26/2021 with c/o 3 days of chest pain 10/10. diagnosed with bilateral descending pulmonary artery pulmonary emboli on CT scan and admitted for further work up and treatment from 3/26-3/28/2021 for b/l PE and hypoxia. Discharged on eliquis with hypoxia resolved.
COVID19 VACCINE	PFIZER\BIONTECH	1171375-1	50-59 years	10-14 days	A perfectly healthy guy, who did not change anything else in his life, got the first vaccination, and 12 days later had a blood clot in his right lung. Went to ER, was diagnosed, and spent 3 days in the hospital. Serious. Doctors so far has no explanation for why this happened.
COVID19 VACCINE	PFIZER\BIONTECH	1173697-1	30-39 years	10-14 days	DVT blood clot in leg. Not able to seek care due to high deductible health insurance. Swelling, pain, discoloration, bruising in lower leg below soleus muscle and deep pain in calf. Using compression, ice, elevation, massage and aspirin regimen.
COVID19 VACCINE	PFIZER\BIONTECH	1175441-1	65+ years	10-14 days	Pulmonary Embolism resulted in emergency care and 4 days in hospital with blood thinners and eventually sent home with having to give self infections and oral blood thinners. All blood tests do not show that it came from a DVT or or that it was inherited therefore, can not show where the dot came from. It is unknown or considered ""Unprovoked"" due to unknown cause. This causes a concern for an adverse reaction from the vaccine""
COVID19 VACCINE	PFIZER\BIONTECH	1179804-1	65+ years	10-14 days	Stroke, pulmonary embolism
COVID19 VACCINE	PFIZER\BIONTECH	1181254-1	65+ years	10-14 days	03-26-2021 patient developed LE pain, progressively worsened. Admitted to hospital on 03/29 and discharged 04/01. Pt diagnosed with superficial femoral artery occlusion and popliteal artery thrombosis. Left femoral artery stent placed 03/31/2021.
COVID19 VACCINE	PFIZER\BIONTECH	1181441-1	30-39 years	10-14 days	PT HOSPITALIZED WITH BLOOD CLOTS IN LUNGS. DISCHARGED FROM HOSPITAL A FEW DAYS LATER.
COVID19 VACCINE	PFIZER\BIONTECH	1185441-1	65+ years	10-14 days	13 days after receiving the second dose I was walking my trash can to the street and I could not breath very well. I went to the Urgent Care and was told I had blood clots in my lungs. I was hospitalized and given treatment for the blood clots.
COVID19 VACCINE	PFIZER\BIONTECH	1185467-1	60-64 years	10-14 days	Developed blood clots in my lungs. Had a pulmonary embolism performed to dissolve the clots.
COVID19 VACCINE	PFIZER\BIONTECH	1186951-1	65+ years	10-14 days	Saddle Pulmonary embolism and right lower extremity DVT
COVID19 VACCINE	PFIZER\BIONTECH	1190415-1	65+ years	10-14 days	Blood clot in brain causing a small stroke affecting right arm, wrist and hand
COVID19 VACCINE	PFIZER\BIONTECH	1196269-1	65+ years	10-14 days	Patient received Pfizer COVID vaccines 1/26/21 and 2/16/21. Developed dyspnea and fatigue 2/2021. Admitted to hospital on 3/2/21 with extensive bilateral acute PE (5 lobes). Right acute occlusive DVT in femoral/popliteal veins and partial thrombosis in the left (age indeterminate) of the femoral and popliteal veins. TTE ok. Started on heparin and transitioned to eliquis (10 BID x7 days then 5 BID). Normal PSA (0.34)
COVID19 VACCINE	PFIZER\BIONTECH	1201053-1	65+ years	10-14 days	1. Acute thromboemboli within the distal right middle cerebral artery M1 segment and proximal right middle cerebral artery M2 segment with intermediate collateral flow. 2. Moderate hypoenhancement of approximately one half of the right middle cerebral artery distribution parenchyma, compatible with oligemia/infarct. Treatment was tPA Discharged from hospital 2/27/2021

COVID19 VACCINE	PFIZER\BIONTECH	1201126-1	50-59 years	10-14 days	Blood clot, stroke, severe headaches, dizziness, vomiting
COVID19 VACCINE	PFIZER\BIONTECH	1202502-1	65+ years	10-14 days	Pulmonary Embolism
COVID19 VACCINE	PFIZER\BIONTECH	1202529-1	18-29 years	10-14 days	Blood clot in left Iliac vein
COVID19 VACCINE	PFIZER\BIONTECH	1203651-1	30-39 years	10-14 days	Pulmonary Embolism - 2 weeks after the shot
COVID19 VACCINE	PFIZER\BIONTECH	1204715-1	65+ years	10-14 days	Blood clot in left leg
COVID19 VACCINE	PFIZER\BIONTECH	1205072-1	60-64 years	10-14 days	Two weeks after 1st Pfizer shot I began to have very heavy breathing while on a daily walk that continued with any exertion. It continued for several days. I called PCP and was seen. Chest Xray & bloodwork was done. Was called to go to E.R. for CT scan of lungs. Pulmonary Embolisms were seen and a blood thinner was given. Heart monitored for previous Afib (ablation performed 5 yrs ago). CT scan w/dye was done of abdomen, Right leg ultrasound with compare L, MRI w/contrast done of abdomen/pelvis. No reason has been found for cause of several blood clots in both lungs - sub arteries. Am being followed up by Vascular Doctors in 2 weeks.
COVID19 VACCINE	PFIZER\BIONTECH	1205187-1	65+ years	10-14 days	developed a small Pulmonary embolism in Lung; Colitis; This is a spontaneous report from a non-contactable consumer (patient, self-reported). A 84-year-old non pregnant patient female received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for injection, Lot number: EL9264 and expiration date was not reported), via unspecified route of administration in left arm on 11Mar2021 at 09:00, at single dose for COVID-19 immunization. The patient's medical history included Myeloma and concomitant medication was not reported. Historical vaccine included first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Lot number: EN6201 and expiration date was not reported), via unspecified route of administration in right arm on 18Feb2021 at 09:30, at single dose for COVID-19 immunization. On 25Mar2021 at 09:30 AM patient developed a small Pulmonary embolism in Lung and Colitis, 10 days after second dose of Pfizer vaccine. The patient had received the treatment medication for the adverse event. The seriousness of the event considered as serious due to hospitalization of the patient. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19 and after vaccination was not tested for COVID-19. The outcome of the events small Pulmonary embolism in Lung and Colitis was recovering. Information on Lot/Batch number was available. Additional information has been requested
COVID19 VACCINE	PFIZER\BIONTECH	1205330-1	30-39 years	10-14 days	Pulmonary Embolism. Pain began in right side rib area on Saturday March 6th. Went to the ER on March 7th late evening. Elevated D-dimer test warranted a CT scan. Scan showed Pulmonary Embolism.
COVID19 VACCINE	PFIZER\BIONTECH	1207333-1	30-39 years	10-14 days	Patient tested positive for COVID on 4/3 or 4/4. Despite this, patient decided to take a road trip since he only had mild symptoms (headache, cough). While he was out of town, his symptoms worsened and he decided to return to home. Patient presented the the ER on 4/13 and was admitted to the hospital for COVID treatment (remdesivir and dexamethasone). He was also found to have a PE and was started on therapeutic Lovenox.
COVID19 VACCINE	PFIZER\BIONTECH	1207346-1	30-39 years	10-14 days	Patient tested positive for COVID on 4/3 or 4/4. Despite this, patient decided to take a road trip to out of state since he only had mild symptoms (headache, cough). While he was in out of state, his symptoms worsened and he decided to return to home state. Patient presented the the ER on 4/13 and was admitted to the hospital for COVID treatment (remdesivir and dexamethasone). He was also found to have a PE and was started on therapeutic Lovenox.
COVID19 VACCINE	PFIZER\BIONTECH	1211576-1	50-59 years	10-14 days	Swelling in left leg around calf and ankle. After a blood test and sonogram a Deep Vein Thrombosis was found in my left leg. Determined ""unprovoked"" by Dr. after subsequent blood test results came back negative. ""
COVID19 VACCINE	PFIZER\BIONTECH	1214358-1	50-59 years	10-14 days	1. Acute left deep venous thrombosis in the popliteal, posterior tibial, peroneal, one branch of gastrocnemius veins. 2. Acute left superficial venous thrombosis in the great saphenous prox thigh to knee extending into a varicose vein at the proximal calf. 1. Pulmonary embolism with large thrombus burden bilaterally, right greater than left ASA/heparin gtt started
COVID19 VACCINE	PFIZER\BIONTECH	1214464-1	60-64 years	10-14 days	Pt developed symptoms of a pulmonary embolism (4/3/21) 10 days after 1st vaccine (3/24/21) Presented to hospital 4/12 with progressive symptoms. Diagnosed and started on blood thinners with tpa administration for severe right heart strain followed by discharge home.

COVID19 VACCINE	PFIZER\BIONTECH	1214500-1	40-49 years	10-14 days	Patient at 27 weeks of pregnancy, reported to midwife at regular visit on 4/14/21 that she was experiencing SOB but all blood work normal - assumed normal SOB with pregnancy. Night/morning of 4/15 started seizures, transported to ED. Diagnosed with massive pulmonary embolism. Emergency C-section performed by Dr. Pt. did not survive.
COVID19 VACCINE	PFIZER\BIONTECH	1215973-1	30-39 years	10-14 days	I began feeling short of breath after doing minor tasks in my own (doing laundry, walking up steps, etc.) during the 2nd week after my covid vaccination. On the morning of April 10th I awoke to feeling severely winded as if I had run 18 marathons just to walk up 3 steps or to walk across a room. I was taken to the ER where they performed a catscan on me and could see that my lungs were ?full? of blood clots and I was experiencing a pulmonary embolism. I do not smoke, take birth control pills, I do not drink. There is no family history of clotting, nor did any traumatic incident happen within the last two weeks to cause this.
COVID19 VACCINE	PFIZER\BIONTECH	1216387-1	65+ years	10-14 days	Developed sudden pulmonary embolism on 4/5/21. No DVT. Very active pt. Unprovoked
COVID19 VACCINE	PFIZER\BIONTECH	1217866-1	50-59 years	10-14 days	Systemic: Blood Disorder (diagnosed by MD)-Severe, Additional Details: Patient hospitalized for blood clot (called pharmacy @ 835pm on 4/15/21). Asked by hospital to contact pharmacy. Patient called from personal phone number.
COVID19 VACCINE	PFIZER\BIONTECH	1218147-1	65+ years	10-14 days	Patient is a 71-year-old female with history of hypertension, hyperlipidemia, and obesity who presents with complaint of acute onset shortness of breath. She reports she was walking around her house earlier when she suddenly became short of breath. She denies any chest pain, numbness or tingling but states that shortness of breath persisted. She denies any tobacco, alcohol or drug use and states she has never had any symptoms similar to this before. Denies any lung disease or heart disease previously. She does have hypertension and hyperlipidemia and is on metoprolol and rosuvastatin respectively which she reports good compliance. Denies family history of MI or strokes. She also denies other symptoms such as nausea, vomiting, abdominal pain, fevers or lower extremity edema. In the ED vitals were found to be within normal limits. EKG was obtained showing diffuse T wave inversions, right bundle branch block, no ST changes, no hypertrophy. Troponin found to be elevated at 0.137, creatinine elevated at 1.3, BUN 26. Chest x-ray was within normal limits. Otherwise lab work was unremarkable. She was given aspirin and Nitropaste Hospital Course: Patient was admitted to the medical floor and remained hemodynamically stable throughout her stay. She actually remained asymptomatic and had no further shortness of breath. She was not hypoxic, at no point required supplemental oxygen. Her troponins however continued to uptrend to 0.389. Cardiology consulted, she was medically optimized with increased statin dose, therapeutic lovenox, and aspirin. Original plan was for cardiac catheterization. However, a d-dimer was ordered which returned elevated to 13.7. CTA was performed which revealed extensive bilateral pulmonary emboli with large clot burden and concern for right heart strain. Echocardiogram showed mildly dilated and hypokinetic RV with mild diastolic dysfunction with impaired relaxation. She was deemed not to be candidate for EKOS. Troponin elevation was felt to be type II NSTEMI 2/2 PE. PE was classified as unprovoked as she has no definite risk factors for this: no prior DVT/PE, no family history of clotting disorder, no evidence of malignancy (UTD with cancer screenings and visits PCP q6m for health maintenance), no cell line abnormalities, no prolonged immobility or long trips or surgeries, no trauma, no hormone or steroid therapies or even antidepressants. She is obese, and has mild CKD. She tested negative for COVID-19 by antigen testing. The only identifiable change in her health habits recently was receiving the first COVID-vaccine dose on 3/18. We discharged her with Eliquis with instructions to taper from 10BID to 5BID after 7 days. As she will be on anticoagulation, the benefit will likely outweigh the risk of receiving the second COVID dose. She will follow up with her PCP and hematology/oncology.
COVID19 VACCINE	PFIZER\BIONTECH	1219629-1	65+ years	10-14 days	EXTENSIVE BLOOD CLOT ,DVT AND PE
COVID19 VACCINE	PFIZER\BIONTECH	1219852-1	65+ years	10-14 days	Patients husband states patient had a DVT and went to hospital. Patient's husband was told for us to report this to VAERs due to her having recent covid vaccine. I do not have specific information regarding length of stay, etc. Pt has recovered.

COVID19 VACCINE	PFIZER\BIONTECH	1224902-1	60-64 years	10-14 days	developed blood clots in lungs; This is a spontaneous report from a contactable consumer (patient). A 63-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: CP6955), via an unspecified route of administration into the left arm on 17Mar2021 as a single dose for COVID-19 immunisation. Medical history included allergies to sulfa. Patient was not pregnant. There were no concomitant medications. The patient previously took amoxicillin and experienced drug allergy. The patient developed blood clots in lungs on 27Mar2021 09:45. The patient was brought to the emergency room and was hospitalized for 3 days. The event was reported as life threatening. It was also reported that the patient was given treatment (unspecified). The patient underwent lab tests and procedures which included SARS-CoV-2 test: negative on 27Mar2021. Outcome of event was recovering.
COVID19 VACCINE	PFIZER\BIONTECH	1227958-1	40-49 years	10-14 days	Blood Clots; Pulmonary Embolisms; DVT (Deep vein thrombosis); This is a spontaneous report from a contactable consumer (patient). A 47-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: ENG207), dose 2 via an unspecified route of administration, administered in Arm Left on 25Mar2021 10:00 (at the age of 47years) as single dose for Covid-19 immunization. The patient received the dose 1 of BNT162B2 via an unspecified route of administration, administered in Arm Left on 04Mar2021 08:30 (Batch/Lot Number: ENG203) as single dose for Covid-19 immunization. The patient is not pregnant at the time of vaccination. Medical history included essential tremor, insulin resistance, and anxiety; all from an unknown date and unknown if ongoing. Concomitant medications included propranolol, metformin, bupropion, and citalopram; all taken for an unspecified indication, start and stop date were not reported. The patient was not diagnosed with COVID-19 prior to vaccination. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient experienced blood clots, pulmonary embolisms, and a DVT (deep vein thrombosis) on 04Apr2021 (11:00AM). The patient was hospitalized due to the events for 4 days. The patient was treated with Heparin and Eliquis. The patient was tested for Covid-19 post vaccination via Nasal Swab on 03Apr2021 with Negative result. The outcome of events was recovering. The adverse events resulted in Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event).
COVID19 VACCINE	PFIZER\BIONTECH	1235735-1	50-59 years	10-14 days	Bilateral Pulmonary Embolism; This is a spontaneous report from a contactable consumer (patient). A 56-years old male patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/Lot Number: EH9899), via an unspecified route of administration on 02Feb2021 (at 56-years-old) as single dose for COVID-19 immunization. Medical history was reported as none. The patient's concomitant medications were not reported. The patient previously took first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/Lot Number: EH9899), on 12Jan2021 (at 56-years-old) for COVID-19 immunization. The patient experienced Bilateral Pulmonary Embolism on 16Feb2021. Facility where the most recent COVID-19 vaccine was administered was at the Workplace clinic. The adverse event resulted Emergency room/department or urgent care. Treatment received for the adverse event was Xarelto 20 mg. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the event was recovering.
COVID19 VACCINE	PFIZER\BIONTECH	1235815-1	50-59 years	10-14 days	stroke; Brain bleed; Brain blood clot; This is a spontaneous report from a contactable consumer via a Pfizer sponsored program named Corporate (Pfizer) Social Media Platforms. A 53-years-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Left on 11Mar2021 13:15 as single dose for covid-19 immunisation. Medical history reported as none. The patient's concomitant medications were not reported. The patient experienced brain blood clot on 25Mar2021 08:00 , stroke and brain bleed on an unspecified date. The patient was hospitalized for brain blood clot, stroke, brain bleed for 7 days. Therapeutic measures were taken as a result of brain blood clot, stroke, brain bleed included Ventilator. The patient died on 02Apr2021. An autopsy was not performed. The outcome of events was fatal. No other vaccine in four weeks; No covid prior vaccination. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: Brain blood clot; stroke; Brain bleed
COVID19 VACCINE	PFIZER\BIONTECH	1245265-1	50-59 years	10-14 days	Right leg popliteal DVT. Symptoms began approximately 3/28/21 (14 days after receiving vaccine), and patient presented to clinic for diagnosis 4/14/21.

COVID19 VACCINE	PFIZER\BIONTECH	1255241-1	65+ years	10-14 days	blood clot in lessor saphenous vein left leg; This is a spontaneous report from a contactable consumer (patient). A 68-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 17Mar2021 at 15:15 (lot number EN6207) as single dose for covid-19 immunization, administered at the hospital. The patient received the first dose on 24Feb2021 at 15:15 in the right arm (lot number EN6198) for covid-19 immunisation. The patient did not receive other vaccines in four weeks. Medical history included type 2 diabetes, deep vein thrombosis (DVT), and pulmonary embolism (PE). The patient has not had COVID prior to vaccination and not tested for COVID post vaccination. The patient's concomitant medications were not reported. The patient experienced blood clot in lessor saphenous vein left leg on 27Mar2021 at 18:00 with outcome of recovering. The patient's hematologist put the patient on Eliquis 5mg 2 BID and at the time of report, this medicine has started to dissolve the clot.
COVID19 VACCINE	PFIZER\BIONTECH	1255644-1	30-39 years	10-14 days	pulmonary embolism; blood clots, her lungs were ""full"" of blood clots; trouble breathing; could barely walk up; This is a spontaneous report from contactable consumer. A 39-year-old female patient received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 25Mar2021 at 11:00AM in left arm at single dose for COVID-19 immunisation. Relevant medical history included minor thalassemia. Past drug history included buprenorphine (SUBLOCADE) taken on 10Mar2021 (location = stomach). Concomitant medications included venlafaxine and zolpidem. The patient had not COVID prior vaccination. The patient began to feel winded doing the most menial of tasks starting the week of 05Apr2021. On the morning of 10Apr2021 she woke up having trouble breathing after walking 10 steps to the bathroom. She could barely walk up 3 steps. It was as if she ran 10 marathons just to get to her bedroom on the second floor (as reported). She went to the ER where a CT scan was performed and it was found that she had a pulmonary embolism and her lungs were ""full"" of blood clots. Onset date for the events was reported as 07Apr2021 at 02:00PM. The events were serious as life-threatening (immediate risk of death from the event) and as causing hospitalization (for 4 days). Procedure to remove clots and heparin were given as treatments. The patient underwent COVID test (nasal swab) post vaccination on 10Apr2021 and result was negative. The events were resolving at the time of report. Information on Lot/Batch number has been requested.""
COVID19 VACCINE	PFIZER\BIONTECH	1255700-1	50-59 years	10-14 days	Felt something in my leg like a cramp / did a scan of my leg and found the clot; dizzy; nearly passed out; This is a spontaneous report from a contactable consumer (patient). A 54-year-old male consumer received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 26Mar2021 at 16:30 at single dose in right arm for COVID-19 immunisation at the age of 54-year-old. Lot number was ER8732. Medical history included Human papilloma virus (HPV) positive tonsil cancer, ankylosing spondylitis, tinnitus, neuropathy, decreased memory from chemo and radiation. The patient did not have Covid prior to vaccination. Concomitant medications were unknown. The patient felt something in leg like a cramp for a week since 06Apr2021 before ER visit. On 06Apr2021, the patient got dizzy at home nearly passed out, and he went to ER. On 14Apr2021, Doctor did a scan of leg and found the clot. The patient was hospitalized due to the events and they were considered life-threatening. The patient was treated with heparin and ELIQUIS. On 14Apr2021, Rapid Covid test was negative. The patient was recovering from the events.

COVID19 VACCINE	PFIZER\BIONTECH	1261769-1	40-49 years	10-14 days	<p>Approximately 2 weeks after the vaccine, inexperienced deep leg pain. 3 days later I went to the hospital and was diagnosed with a blood clot/DVT.; Approximately 2 weeks after the vaccine, inexperienced deep leg pain. 3 days later I went to the hospital and was diagnosed with a blood clot/DVT.; Approximately 2 weeks after the vaccine, inexperienced deep leg pain. 3 days later I went to the hospital and was diagnosed with a blood clot/DVT.; This is a spontaneous report from a contactable consumer. A 46-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration, administered in Arm Left on 25Mar2021 13:00 (Batch/Lot Number: ER2613) as SINGLE DOSE for covid-19 immunisation. Medical history included none. The patient's concomitant medications were not reported. Approximately 2 weeks after the vaccine, inexperienced deep leg pain. 3 days later, the patient went to the hospital and was diagnosed with a blood clot/DVT. AE resulted in: [Emergency room/department or urgent care]. The patient received treatment for the events: Vitals taken, blood work, prescribed blood thinner. The patient underwent lab tests and procedures which included blood test: unknown result on an unspecified date ae treatment= Vitals taken, blood work , investigation: blood clot/dvt on 08Apr2021 3 days later I went to the hospital and was diagnosed with a blood clot/DVT, investigation: unknown result on an unspecified date ae treatment= Vitals taken, blood work. The outcome of the event was recovering. The patient does not have COVID prior vaccination, and was not COVID tested post vaccination. The patient has no known allergies.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1261796-1	30-39 years	10-14 days	<p>Pulmonary Embolism; This is a spontaneous report from a contactable consumer (patient). A 33-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: FN6206), via an unspecified route of administration in the right arm, on 16Mar2021 at 14:00 (at the age of 33-years-old) as a single dose for COVID-19 immunisation. The patient had no medical history or concomitant medications. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient had no known allergies. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced pulmonary embolism on 30Mar2021 at 00:00 (reported as: 12:00 AM), which caused hospitalization. The patient underwent lab tests and procedures which included COVID-19 nasal swab: negative on 30Mar2021. Therapeutic measures were taken as a result of the event, which included apixaban (ELIQUIS). The clinical outcome of pulmonary embolism was recovering.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1261806-1	65+ years	10-14 days	<p>blood clot in my lungs/Multiple blood clots; Pains; This is a spontaneous report from a contactable consumer. This 69-year-old female consumer reported for herself that: Patient characteristics: Weight (kg): 102.97 Height (cm): 165 Sex: Female Relevant medical history and concurrent conditions: Structured information (Patient episode name): Hypertension Patient Medical comments: Verbatim: Hypertension Reaction(s)/Event(s): Reaction/event as reported by primary source: Blood clot in my lungs within the first 2 weeks after the second shot Reaction(s)/Event(s): Reaction/event as reported by primary source: Hospitalization Reaction/event in MedDRA terminology (LLT): Hospitalization Reaction/event MedDRA term (PT): Hospitalisation Reaction(s)/Event(s): Reaction/event as reported by primary source: Pains Results of tests and procedures for investigation of the patient: Test: CTA scan More information available (Y/N): No Drug(s) Information: Characterization of drug role: Suspect Proprietary medicinal product name: Covid-19 Vaccine Batch/lot number: ER8732 Date of start of drug: 30Mar2021 Action(s) taken with drug: Unknown Drug(s) Information: Characterization of drug role: Concomitant Proprietary medicinal product name: Lisinopril HCTZ Dosage text: 20-25 mg Tablet Indication for use in the case: Hypertension Narrative case summary and further information: Case narrative: Selected Report Type: Initial Patient Ethnicity: (Ethnicity withheld) Is the patient also the reporter? Yes Reporter type: Consumer or other non-health professional Reporter telephone: (Phone no withheld) Primary / Prescribing Healthcare Professional Info Dates for Blood clot in my lungs within the first 2 weeks after the second shot.: (From: Unspecified To: Unspecified) Dates for Hospitalization: (From: Unspecified To: Unspecified) Dates for Pains: (From: Unspecified To: Unspecified) Is Covid-19 Vaccine a Pfizer product? Yes Covid-19 Vaccine manufacturer: Unspecified Dates for Covid-19 Vaccine: (Start: 30Mar2021 Stop: Unspecified) NDC number of Covid-19 Vaccine: Unknown UPC number of Covid-19 Vaccine: Unknown Expiry Date of Covid-19 Vaccine: 31Jul2021 Other Products: Yes Dates for Concomitant Products Lisinopril HCTZ: (Start: Unspecified Stop: Unspecified) Patient History: Yes Patient history: Hypertension (From: Unspecified To: Unspecified) Investigation Assessment: Yes Investigation: CTA scan (Date: Unspecified, Result / Units: ) Additional Context: Consumer stated, ""I could not follow on the parts. So may be should have done certainly but I am not technically astute. So, I wanted to report that I just had the second Covid-19 test and as a experience in emergency room discovery of blood clot in my lungs within the first 2 weeks after that second shot. So, I wanted to report that. Is this the place I do that?"" When paraphrased, consumer stated, ""Multiple blood clots."" Start date of event (Multiple blood clots.): Consumer stated, ""10Apr2021. I should probably say that the pains were 09Apr. I went in the emergency room on the 10th. So, I am not sure which day."" Treatment :Consumer stated, ""Yes, I went To the emergency room and was kept in the hospital and then I saw my own Doctor just today who is going to help me try to determine what is going to happen next ? I was released by the hospital."" Details of hospitalization: Duration of hospitalization: 24 hrs. (overnight) Date of Admission:10Apr2021 Date of Discharge:11Apr2021 Lab work: Consumer stated, ""They did lab. work while in the emergency room and in the hospital. They did Chest CTA scan."" This is a spontaneous report from a contactable consumer. A 69-year-old female patient received second dose of</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1261816-1	50-59 years	10-14 days	<p>had pulmonary embolism in both lungs; blood clots/blood clots in the lungs; This is a spontaneous report from a contactable consumer (patient). A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 2 via an unspecified route of administration administered in arm right on 07Apr2021 at vaccination age of 54 years old (Lot Number: EN6208; Expiration Date: Jun2021) as single dose for covid-19 immunisation. There was no medical history. No known allergies. No Covid prior vaccination. The patient's concomitant medications were not reported. The patient previously took BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration administered in arm left on 08Mar2021 14:00 at vaccination age of 54 years old (Lot Number: EN6205; Expiration Date: 30Jun2021) as single dose for covid-19 immunisation. No other vaccine in four weeks. No other medications in two weeks. The patient experienced had pulmonary embolism in both lungs on 17Apr2021 13:00, blood clots/blood clots in the lungs on 17Apr2021 13:00. Events resulted in emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event), disability or permanent damage. The patient had pulmonary embolism in both lungs. He was in the hospital for 3 days and now he will have to take blood thinners in definitely. He was admitted 17Apr2021 and discharged home 19Apr2021. He did not have history of blood clots and zero risk factors. Two doctors blamed the vaccine. He did not want to take blood thinners forever. He needed help figuring out how to determine if this was related to the vaccine. He had a reaction to the second shot and he had been in the hospital the last 3 days and the 2 different doctors that saw him said the only thing that was different was that he had received the COVID vaccine. He had blood clots in both of his lungs, he was in serious condition for a couple days there but his biggest concern now was that they were telling him that he will have to take medication forever to thin his blood because they didn't think there was a genetic reason it happened and that was the protocol that healthcare providers have to follow. They were telling him that he might contact a hematologist and do a blood study but they said they were certain that it came from the vaccine because there was no history of this in his family or himself. He said the condition's medical term was pulmonary embolism but he just said blood clots in the lungs because he thought he would make it easier to explain. Both doctors that saw him felt it was brought on the by the vaccine. He was not looking to sue or anything, he didn't want to be taking a blood thinner for the rest of life. He was not doing this for any reason other than to get well. He realized this situation was very rare with Pfizer, it was like 4 in 1 million with Pfizer according to his physicians. Covid tested post vaccination: Nasal Swab on 17Apr2021 with negative result. Therapeutic measures were taken as a result of had pulmonary embolism in both lungs, blood clots/blood clots in the lungs. The outcome of events was recovered with sequelae.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1261820-1	65+ years	10-14 days	<p>102 deg F temp; shivering; abnormal general body fatigue; Atelectasis; double blood clot in left lung lower left lobe; This is a spontaneous report from a contactable consumer (Patient). A 68-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration, administered in Arm Right on 01Apr2021 17:00 (Batch/Lot number was not reported) at the age of 68-years-old as single dose for covid-19 immunisation. The COVID-19 vaccine was administered at Doctor's office/urgent care. Medical history included Inclusion Body Myositis, Sjogren's syndrome and Known allergies included Penicillin, Lamisil, Sulfa drugs. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient concomitant medication included unspecified other medications in two weeks. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Got up 9:30AM on 14Apr2021. Experienced abnormal general body fatigue. Began shivering at 1:00 PM and went back to bed. 102 degree F temp at 3:00 PM. Called primary care physician, who advised we go to Emergency room (ER). Got into ER about 6:00pm. Covid polymerase chain reaction (PCR) Nasal Swab test negative, full viral panel negative. Chest X-Ray showed some Atelectasis, Computerised tomogram (CAT) scan revealed double blood clot in left lung lower left lobe. Sent to Hospital at about 1:00 AM 15Apr2021. Treatment with 16ml/hr Heparin plus 5mg/day warfarin. Discharged 06:00 PM on 16Apr2021. Adverse event resulted in: [Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event)]. The outcome of the events was recovering. Information on the lot/batch number has been requested.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1263560-1	65+ years	10-14 days	Per patient's Daughter the patient developed blood clots in his small intestine on 4/13/2021 and died 4/22/21 with physicians unable to explain how or why he developed these clots while on apixaban. She requested his case be reported and reviewed in hopes it helps make the vaccines safer if that was what caused the clots.
COVID19 VACCINE	PFIZER\BIONTECH	1265982-1	65+ years	10-14 days	Blood clot in her lower abdominal area; had the worst pain through her side that ran down her left leg and to her ankle; had the worst pain through her side that ran down her left leg and to her ankle; nerves are all tangled up; This is a spontaneous report from a contactable consumer (patient). A 76-year-old female patient received the second dose of bnt162b2 (BNT162B2, Solution for injection, Lot Number: EN6207), via an unspecified route of administration, administered in Arm Right on 17Mar2021 13:50 (at 76-years-old) as single dose for COVID-19 immunisation. The vaccine was administered at a hospital. It was not administered at a military facility. Medical history included hip replacement four years ago in 2017 (First right then 2 months later left) and knee replacement six years ago in 2015 (both 2 months apart). There were no concomitant medications. The patient previously received the first dose of bnt162b2 (BNT162B2, Solution for injection, Lot Number: EN6203), administered in Left Arm on 25Feb2021 (at 76-years-old) for COVID-19 immunisation and experienced bad headaches. The patient received the second dose of vaccine on 17Mar2021. On 29Mar2021, she was not hurting and went to brunch with friends. Afterwards (on the same date, 29Mar2021), she was sitting and got the worst pain through her side that ran down her left leg and to her ankle. She drove herself home but was in such misery. She went to the emergency room the next day, on 30Mar2021, wherein she had a CT (computerized tomography) scan that showed a blood clot in her lower abdominal area. She was taking pain medication every 6 hours, or she could hardly stand it. On 08Apr2021, she went back to the emergency room because she could hardly stand it. She was kept in observation status but was not admitted. She was scheduled to have another CT scan on 06May2021. She is not sure what they will do because the nerves are wrapped around it. She also mentioned that her doctor wants to do a biopsy. The pain was also running down to her ankle. She stated that she has had both of her hips replaced in the past. She added that her doctor will do an MRI (magnetic resonance imaging). He will put in a drain if it has not shrunk. The doctor can't do anything because the nerves are all tangled up (2021). As corrective treatment, the patient was taking pain medication for the blood clot and pain through her side that ran down her left leg and to her ankle. Outcome of nerves are all tangled up was unknown, while outcome of the other events was not recovered.
COVID19 VACCINE	PFIZER\BIONTECH	1265997-1	50-59 years	10-14 days	This is a spontaneous report from a contactable consumer, the patient. This 53-year-old male patient reported that he received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot Number: UNKNOWN) via an unspecified route in the left arm on 28Mar2021 at 12:00 (at the age of 53-years-old) as a single dose for COVID-19 immunization. Medical history was reported as healthy. The patient had a known allergy to amoxicillin/clavulanic acid (AUGMENTIN). The patient did not receive any other vaccines within four weeks. The patient did not have COVID prior to the vaccination. Concomitant medication included over the counter (OTC) product (unspecified). Ten days after (as reported), on 10Apr2021, the patient had blood clot in retina of eye which caused temporary blindness. The events resulted in: Doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care. The patient was doing additional testing to see what damage occurred (test name and results not provided). The patient was not treated for blood clot in retina of eye and temporary blindness. The clinical outcomes of blood clot in retina of eye and temporary blindness was unknown. The patient was not tested for COVID-19 post vaccination. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.

COVID19 VACCINE	PFIZER\BIONTECH	1266045-1	50-59 years	10-14 days	15cm Blood clot in left leg - lower calf.; Superficial vein prominence; This is a spontaneous report from a contactable consumer (patient herself). This 50-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number ER8732), via an unknown route in the left arm, on 27Mar2021 at 14:45 (at the age of 50-year-old) at single dose for COVID-19 immunisation, administered at hospital. Relevant medical history included Factor V Leiden and varicose veins. The patient did not have allergies. The patient did not have COVID-19 before vaccination. Relevant concomitant medications included acetylsalicylic acid (ASPIRIN), levothyroxine sodium and Women's multivitamin (unspecified). On 07Apr2021, the patient presented 15 cm blood clot in the left leg-lower calf and superficial vein prominence. The events required a physician office visit. An ultrasound was done but results were not provided. Therapeutic measures taken as result of the events included enoxaparin sodium (LOVENOX) injections for 14 days. Post-vaccination COVID test was not performed. The patient was recovering from the events.
COVID19 VACCINE	PFIZER\BIONTECH	1269525-1	65+ years	10-14 days	atrial fibrillation; atrial fibrillation; splenic infarction; extreme left upper abdominal pain; large portion of his spleen unusable; blood clots causing that portion of his spleen to die; blood clots causing that portion of his spleen to die; This is a spontaneous report from a contactable consumer (patient). A 68-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot: EN6206), via an unspecified route of administration in right arm on 23Mar2021 09:00 (at the age of 68-years-old) as single dose for covid-19 immunisation. The vaccination facility type was a health department. Medical history included atrial fibrillation (under control with medicine). The patient's concomitant medications were not reported. The patient previously took ciprofloxacin hydrochloride (CIPRO) and experienced allergies: Cipro. The patient had no COVID prior vaccination and was not COVID tested post vaccination. No other vaccine in four weeks. It was reported that within 13 days of the injuction (on 06Apr2021 at 04:00), the patient had three atrial fibrillation events on three separate days between 01:00 and 03:00 while sleeping and on day 13 was admitted to the hospital with extreme left upper abdominal pain they diagnosed with splenic infarction and rendering a large portion of his spleen unusable from blood clots causing that portion of his spleen to die. Now the patient have to take blood thinners the rest of his life. The events resulted in emergency room/department or urgent care, hospitalization for 1 day, disability or permanent damage. The events treatment included several pain shots administered then given enoxaparin sodium (LOVENOX). The outcome of the events was recovered with sequel.
COVID19 VACCINE	PFIZER\BIONTECH	1269558-1	65+ years	10-14 days	massive pulmonary embolism in both lungs; This is a spontaneous report from a contactable consumer. A 77-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in arm left on 08Mar2021 10:40 (Batch/Lot Number: EN6199) at 0.3 mL, single dose for COVID-19 immunization. Medical history included overweight and high blood pressure. Family history of her sister included medical conditions after dementia including a blood clot in pancreas and leg a few years ago. Her other sister had a blood clot in her leg within the last year. The patient's concomitant medications were not reported. The first dose of the Covid-19 vaccine on 08Mar2021. On 17Mar2021 she had symptoms and went to the emergency room on 18Mar2021. She was diagnosed with a massive pulmonary embolism in both lungs. She had a procedure and was in ICU for 2.5 days. They put a needle in her arm and gave her medication for the blood clots and monitored her very closely for two hours. They continued to monitor her for 24 hours but not as close. There was no previous immunization/ vaccination and no vaccine administered on the same date of the Pfizer suspect. The event required a visit to the emergency room and was hospitalized for 3 days (18Mar2021-21Mar2021). She does not have the results of any tests that were performed. The outcome of the event was unknown.

COVID19 VACCINE	PFIZER\BIONTECH	1269707-1	65+ years	10-14 days	left leg deepvein thrombosis; blood clot; This is a spontaneous report from a contactable consumer (patient). A 73-year-old male patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EL9269), via an unspecified route of administration, administered in Arm Right on 12Feb2021 19:30 (7:30 pm) as single dose for COVID-19 immunization in a hospital. Medical history included high blood pressure and high cholesterol both from an unknown date. No known allergies. The patient took an unspecified medication. No other vaccines in four weeks. No COVID-19 prior to vaccination. The patient received the first dose of bnt162b2 (lot number: EL9261) on 22Jan2021 07:15 am on the right arm for COVID-19 immunization. On 25Feb2021 21:00 (9:00 pm), the patient experienced left leg deep vein thrombosis and blood clot which required a visit to the emergency room and subsequent hospital admission. The patient was given Eliquis as treatment. The patient was tested for COVID-19 post vaccination via nasal swab on 08Apr2021 with a negative result. The outcome of the events was reported as recovering.
COVID19 VACCINE	PFIZER\BIONTECH	1278497-1	30-39 years	10-14 days	Pulmonary embolism with pulmonary infarction; Pulmonary embolism with pulmonary infarction; This is a spontaneous report from a contactable physician. A 38-year-old male patient received second dose of BNT162B2 (Batch/Lot number was not reported), intramuscular on Apr2021, at 38 years old, as a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient previously took first dose of BNT162B2 intramuscular on Mar2021 at 38 years old as single dose for COVID-19 immunisation. On 15Apr2021, the patient experienced pulmonary embolism with pulmonary infarction and patient was hospitalized for 1 day. The events resulted in Emergency room/department or urgent care and Hospitalization. It was unknown if the patient received any other vaccines within four weeks prior to the vaccination and medications within two weeks prior to the vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient underwent lab tests and procedures which included Nasal Swab: negative on 15Apr2021. Therapeutic measures were taken as a result of pulmonary embolism with pulmonary infarction which included anticoagulation. The outcome of the events was recovering. Information on the lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Committees, and Investigators, as appropriate
COVID19 VACCINE	PFIZER\BIONTECH	1278538-1	50-59 years	10-14 days	Woke up with chest pains diagnosed as blood clots in both lungs.; Mental confusion; This is a spontaneous report from a contactable consumer reporting for herself. A 56-years-old female patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration, administered in Left Arm on 31Mar2021 13:00 (Batch/Lot Number: ER8730) as single dose for covid-19 immunisation . Medical history included sleep apnoea syndrome , depression , drug hypersensitivity to penicillin. Concomitant medications included escitalopram (ESCITALOPRAM) taken for an unspecified indication, start and stop date were not reported; meloxicam (MELOXICAM) taken for an unspecified indication, start and stop date were not reported. The patient previously took Biaxin and experienced drug hypersensitivity, first dose of bnt162b2 for covid-19 immunisation on 10Mar2021. The patient woke up with chest pains diagnosed as blood clots in both lungs on 10Apr2021 08:30 with outcome of recovering , mental confusion on 10Apr2021 08:30 with outcome of recovering. The patient was hospitalized for 3 days because of the events. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 14Apr2021 . The patient is receiving apixaban (ELIQUIS) as treatment of the reported events. Follow up information has been requested. Lot number already received.

COVID19 VACCINE	PFIZER\BIONTECH	1278714-1	65+ years	10-14 days	<p>A little over a week after the First vaccination, I developed two blood clots in my leg; This is a spontaneous report from a contactable consumer (patient). A 67-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: unknown), dose 1 via an unspecified route of administration, administered in the left arm on 18Mar2021 as SINGLE DOSE, for covid-19 immunization (at the age of 67 years-old). The patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: unknown), dose 2 via an unspecified route of administration, administered in the left arm on 14Apr2021 as SINGLE DOSE. The patient was not pregnant at the time of vaccination. The patient did not receive any other vaccine within 4 weeks prior to the vaccine. Medical history included peripheral arterial occlusive disease from an unknown date and unknown if ongoing and bad circulation. There were no known allergies. Prior to the vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any concomitant medications. The patient developed two blood clots in her leg on 28Mar2021 a little over a week after the first vaccination. There was no treatment provided for the blood clots. The outcome of the blood clots was not recovered. It was also reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible; information about lot/batch number cannot be obtained.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1278778-1	40-49 years	10-14 days	<p>calf feels tight, stiff, it feels like dead weight/started within the last 2- 3 weeks; calf feels tight,; pain running up the right arm up to the shoulder; pain running up the right arm up to the shoulder/his calf pain, started to feel tight, started within the last 2- 3 weeks; He asks if someone can tell him if it is a blood clot in the back of his calf; his eyes also hurt a little bit; This is a spontaneous report from a contactable consumer (patient). A 46-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), second dose at the age of 46-years-old via an unspecified route of administration, administered in arm left on 02Apr2021 (Batch/Lot Number: ER8734) as single dose for covid-19 immunisation. There was no medical history reported. There were no concomitant medications. The patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 12Mar2021 (lot number: EN6202) at the age of 46-years-old for covid-19 immunisation and experienced If it is a blood clot in the back of his calf, Regular pain feeling, Headache, Muscle pain, Calf feels tight, stiff, it feels like dead weight, Pain running up the right arm up to the shoulder and Calf pain, started to feel tight. The patient reported that he has been feeling the regular pain feeling, a headache, muscle pain before, it comes and goes on 12Mar2021. However, he says that the last few days there had been, by his calf muscle in the back there, they've been tightening, like stiffening up on him when he's sleeping on an unspecified date. It wakes him up at times. He also reports pain running up the right arm up to the shoulder on an unspecified date. He says he is just curious in terms of what that might be. He asks if someone can tell him if it is a blood clot in the back of his calf on an unspecified date. The headache went away after 2-3 days. He says his eyes also hurt a little bit on 12Apr2021 and was the same time frame as the headache. He says those things were just mild, nothing major. He did not take anything for it. He confirmed he no longer has muscle pain. He just has pain behind the calf and right arm up to his shoulder. He says his calf pain, started to feel tight, started within the last 2- 3 weeks. The arm pain in right arm up to shoulder started maybe within the last 2 days. The outcome of the events was unknown. Follow-up attempts completed. No further information expected.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1279144-1	40-49 years	10-14 days	Passed out; Blood clots in lungs; almost died from the vaccine; Problem in breathing; This is a spontaneous report from a contactable consumer (patient) reported that a 48-year-old patient of an unspecified gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3247), via an unspecified route of administration, administered in arm right on 21Jan2021 (at the age of 48-years-old) as a single dose for covid-19 immunisation. The patient was healthy and had no suffering from any medical condition. Concomitant medication included sertraline hydrochloride (ZOLOFT) taken for an unspecified indication, start and stop date were not reported. The patient had his/her shot on 21Jan2021 and about 10 days later he/she was having problem in breathing. When the patient went to work, he/she passed out at work and they sent him/her to the hospital and he/she wound up in the hospital on 12Feb2021 and they found out that he/she have blood clots in his/her lungs. The patient added that the matter of concern was he/she almost died from the vaccine. The patient was discharged on 14Feb2021 and he/she went in on 12Feb2021 and they did the catheter to remove the blood clot. The patient was hospitalized due to blood clots in his/her lungs and prior to going to the hospital, a week, and a half before that he/she was having breathing issues. The patient underwent lab tests and procedures which included blood test with unknown results on Feb2021. The patient was supposed to get the 2nd dose on 11Feb2021, but he/she never went because he/she wound up in hospital. The patient right now was taking blood thinner named Eliquis after he/she wind up with clot. The outcome of the events was unknown.
COVID19 VACCINE	PFIZER\BIONTECH	1294744-1	60-64 years	10-14 days	urinating blood; might be a UTI; arm pain; fatigue; blood clots; he started bleeding after the first shot; This is a spontaneous report from a contactable consumer, the patient. This 63-year-old male patient reported that he received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot Number: EL3249) on 18Feb2021 (also reported as 17Feb2021) (at the age of 63-years-old) via an unspecified route as a single dose for COVID-19 immunization. Medical history included enlarged prostate, urinary health issues (gets up in the middle of the night), and has glasses as he had cataract surgery last year (2020) so he lost his close-up vision. Concomitant medications were not reported. On 18Feb2021, the patient got his first shot. Three weeks later, he had an episode of urinating blood and blood clots profusely. The patient stated the amount of blood and blood clots was scary at best. The patient reached out to his daughter who is a nurse who advised him to go to the Emergency Room (ER). He reached out to the nurse hotline as well, which recommended that he go to the emergency room that day as well. He went to the ER (it was a Sunday). They did a blood test, a sonogram or some kind of sonogram, and a urine sample. They also flushed the patient's bladder out with a catheter. This emergency room visit determined that it might be a urinary tract infection (UTI) and started him on antibiotics. The patient confirmed he was not admitted to the hospital. The patient then made an appointment with his doctor because that was on a weekend. He saw his doctor who referred him to a urologist. The patient also reported that he did have the normal arm pain and fatigue the second day or the day after the shot. The patient reported 11Mar2021 or 12Mar2021 was when he started bleeding after the first shot, he was unsure of the exact date, and stated he went to the hospital on 14Mar2021. The patient reported he is going to the doctor today (21Apr2021), to see the urologist but the urologist is going to do a scope in his bladder because that is the only thing that they cannot see. The clinical outcome of events urinating blood, blood clots, UTI, bleeding, arm pain, and fatigue was unknown.; Sender's Comments: Linked Report(s) :PFIZER INC-2021471072 same patient/reporter, different AE/2nd dose
COVID19 VACCINE	UNKNOWN MANUFACTURER	1201229-1	65+ years	10-14 days	SOB, DOE, pleuritic chest pain x2 weeks progressively worsened, the patient presented to hospital and was later transferred to secondary hospital.
COVID19 VACCINE	UNKNOWN MANUFACTURER	1204289-1	40-49 years	10-14 days	Woke with nausea, vomiting, climbing fever upto 103, body aches, chills on 4/5/21. Symptoms resolved but felt tired on 4/6/21. Morning of 4/7/21, woke with shortness of breath and chest pain. Negative COVID-19 test. Went to hospital and did a cardiac workup and blood work, CT scan followed that showed several blood clots in lungs. Was given heparin bolus, and continued for an additional day, then switched to Eliquis. Hospitalization duration was 2.5 days.
COVID19 VACCINE	UNKNOWN MANUFACTURER	1214759-1	50-59 years	10-14 days	Pain, swelling left knee found to be a blood clot when he went to the Emergency Room at hospital. Visit was on 3/31/2021 Treatment with rivaroxaban and bed rest. Pain and muscle spasms persist as of 4/15/2021
COVID19 VACCINE	JANSSSEN	1206172-1	50-59 years	Over 120 days	Severe blood clots,surgery sbc filter

COVID19 VACCINE	JANSSEN	1241934-1	50-59 years	Over 120 days	Pt was vaccinated on 3/16/2021 with J&J COVID 19 vaccine. Pt developed increasing URI sx @ 4/5/2021. The symptoms progressed and she noticed that she was feeling more and more sob, fatigued, and had developed some mild cp. She presented with a pulse ox of 94% on RA. No acute distress. Lung sounds diminished.
COVID19 VACCINE	MODERNA	1096519-1	65+ years	Over 120 days	Multiple pulmonary embolisms both right and left lungs , coughing up blood 5 days after second moderne shot. Very healthy non smoker , no history of heart problems. Non drinker, Heath professional DDS degree.
COVID19 VACCINE	MODERNA	1189625-1	65+ years	Over 120 days	Deep vein thrombosis; This spontaneous case was reported by an other health care professional (subsequently medically confirmed) and describes the occurrence of DEEP VEIN THROMBOSIS (Deep vein thrombosis) in a 73-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Co-suspect product included non-company product IBRUTINIB (IMBRUVICA) tablet for CLL. The patient's past medical history included Blood immunoglobulin G (low levels from past 20 years). Concurrent medical conditions included Chronic lymphocytic leukemia, Depression, Drug allergy (allergic reaction to Rituxan.) and Glaucoma. Concomitant products included FLUOXETINE HYDROCHLORIDE (PROZAC) for an unknown indication. In February 2020, the patient started IBRUTINIB (IMBRUVICA) (unknown route) 420 milligram once a day. On 20-Dec-2020, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 08-Jan-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. In January 2021, the patient experienced DEEP VEIN THROMBOSIS (Deep vein thrombosis) (seriousness criterion medically significant). At the time of the report, DEEP VEIN THROMBOSIS (Deep vein thrombosis) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In January 2021, SARS-CoV-2 antibody test (610-1600): 347 (Negative) 347. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Other history included:no alcohol use, no drug abuse, non smoker Treatment information were not provided. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, the patient's past medical history of CLL and drug IBRUTINIB can contribute to this event. further information has been requested Reporter did not allow further contact; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, the patient's past medical history of CLL and drug IBRUTINIB can contribute to this event. further information has been requested
COVID19 VACCINE	PFIZER\BIONTECH	0957555-1	30-39 years	Over 120 days	I am a registered nurse at hospital. On 12/25, seven days after receiving the shot I started to get right lower leg pain and I kept complaining about it till New Years Day. I had no symptoms of a DVT. I triaged on 1/1/21 and the doctors ordered labs/imaging and the results were as followed: D-Dimer biomarker (+), Ultrasound of the Rt lower leg (-), CTA showed a PE (segmental right upper lobe pulmonary artery consistent with pulmonary embolus). I was discharged on Xarelto and advised to follow up with a hematologist. On 1/5/2021, I went to hematology and they did a whole bunch of labs. I was sent to get a ultrasound of the leg because the pain persist and they found a dot hidden by my soleus. The plan is to continue on the Xarelto for 6 months. Come back in 3 weeks to scan my leg again and get my lab results. On 1/12/2021, I received the 2nd shot of the Pfizer vaccination.
COVID19 VACCINE	PFIZER\BIONTECH	1069774-1	65+ years	Over 120 days	shortness of breath, dyspnea on exertion that started after 2nd vaccine, found to have pulmonary embolism 2 weeks later
COVID19 VACCINE	PFIZER\BIONTECH	1215846-1	65+ years	Over 120 days	Severe abdominal pain,nausea,emergency hospital visit,atrial fibrillation,thrombosis,left.kidney infarct.admittance to local hospital for 5 days and ongoing follow up testing and multiple specialist visits for months
COVID19 VACCINE	JANSSEN	1162619-1	18-29 years	15-30 days	Superior sagittal sinus thrombosis diagnosed on 4/1/2021. Symptoms started early on April 1, 2021
COVID19 VACCINE	JANSSEN	1164783-1	30-39 years	15-30 days	Pulmonary embolism and bilateral DVTs, received vaccine on 3/11/21, was admitted to the hospital on 3/29/21
COVID19 VACCINE	JANSSEN	1190592-1	50-59 years	15-30 days	Bilateral Pulmonary Embolism

COVID19 VACCINE	JANSSSEN	1199203-1	50-59 years	15-30 days	Patient had a large pulmonary embolism 3 weeks after receiving the vaccine. Unclear if vaccination was the cause, but giving the timing we are reporting it. The health care proxy also noted some palpable masses on distal L extremity, unclear if related to vaccine or what these are.
COVID19 VACCINE	JANSSSEN	1199238-1	50-59 years	15-30 days	Approximately three weeks after receiving Johnson & Johnson vaccine, I began to get pains in legs. Calves were aching and throbbing. Didn't think anything of it at first....just thought achy muscles and such. The day before Easter (April 3rd 2021) decided since the pain was continuing and the internet will scare you to death - I went to a local Emergency Room in advance, I had an ultrasound on my left leg and it was noted I had DVT. (blood clot in left calf) To briefly explain: I had an achilles issue back in Nov. 2020 (slight micro tear - achilles tendonitis) I thought maybe this was related to that, as I had not been to the doctor to get it checked until early March 2021. and it bothered me off and on for a few months. I thought the calf pain may have been related to that? I explained to the emergency room doctor about my achilles and thought it was an issue related to that. They decided to perform an ultrasound on my left leg. Which noted the DVT/Blood Clot. They put me on a starter pack of Xarelto and I am to follow up with my normal doctor on April 22, 2021.
COVID19 VACCINE	JANSSSEN	1200280-1	65+ years	15-30 days	She had Pulmonary embolism
COVID19 VACCINE	JANSSSEN	1200312-1	65+ years	15-30 days	On March 27, 2021 the patient developed some pleuritic chest pain and shortness of breath. he went to the Emergency Department at Hospital.
COVID19 VACCINE	JANSSSEN	1200641-1	30-39 years	15-30 days	Occlusive superficial thrombus developed to lesser saphenous vein extending toward popliteal vein within 2 cm, developed ~2 weeks after vaccination.
COVID19 VACCINE	JANSSSEN	1200648-1	50-59 years	15-30 days	Developed DVT in right calf on March 23, 2021.
COVID19 VACCINE	JANSSSEN	1200992-1	30-39 years	15-30 days	I developed leg pain in my right leg 2 weeks after vaccination. A week later, I went to the hospital and they confirmed ""Acute deep vein thrombosis) DVT of calf muscle vein of right lower extremity"" and at least one additional superficial clot. I was prescribed blood thinners apixaban (Eliquis) and was discharged. I'd previously had a clot in the same leg in 2009.""
COVID19 VACCINE	JANSSSEN	1201055-1	65+ years	15-30 days	Shortness of breath and rushed to ER - they found massive blood clot in both lobes of my lungs. No sign of Deep Vein Thrombosis - seems a mystery. Almost fatal if not gotten to ER so quickly they said. I was in the ICU from 4/7 - 4/10
COVID19 VACCINE	JANSSSEN	1201098-1	65+ years	15-30 days	After having hard time breathing for over a week, finally went to er on April 5
COVID19 VACCINE	JANSSSEN	1201107-1	50-59 years	15-30 days	Right leg DVT
COVID19 VACCINE	JANSSSEN	1201178-1	40-49 years	15-30 days	Shortness of breath and leg pain times 3 days. Diagnosed with Pulmonary Embolus on April 8,2021
COVID19 VACCINE	JANSSSEN	1201200-1	40-49 years	15-30 days	Dermatitis on torso, hands and feet, skin peeling on left foot A few nosebleeds with small clots
COVID19 VACCINE	JANSSSEN	1201222-1	18-29 years	15-30 days	small blood clot when tried to donate blood 2.5 weeks after shot, preventing me from finishing donation
COVID19 VACCINE	JANSSSEN	1201374-1	50-59 years	15-30 days	On 4/3/21 the patient presented with a 1 week history of slowly progressive shortness of breath and 3 day history of left upper quadrant pain. CT revealed bilateral segmental and subsegmental pulmonary emboli, moderate splenic enlargement, and small volume perisplenic hemorrhage. Continuous infusion heparin was started for the bilateral PE. On 4/4 an inferior vena cava filter was placed and patient was vaccinated with Acthib, Bexsero, and Prevnar vaccines in anticipation of splenectomy. On 4/7 a laparoscopic splenectomy was performed. The spleen was evaluated by pathology which reported ""Organizing blood clot on surface, consistent with rupture. No evidence of malignancy."" The patient remains inpatient while recovering from surgery. On 4/12 she was transitioned to rivaroxaban for therapeutic anticoagulation. Please note as of 4/13 the patient remains hospitalized.""
COVID19 VACCINE	JANSSSEN	1201386-1	50-59 years	15-30 days	developed a rare disorder involving blood clots within about two weeks of vaccination.
COVID19 VACCINE	JANSSSEN	1201482-1	50-59 years	15-30 days	Patient had the vaccine on 3/5/21. She then had major abdominal surgery which included abdominal reconstruction, hernia repair and excess skin removal on 3/19/21. She was released from the hospital on 3/22/21. She was readmitted on 4/4/21 for blood clots.
COVID19 VACCINE	JANSSSEN	1201922-1	65+ years	15-30 days	I received the vaccine on March 8th, and got dizzy and was taken to Hospital by Ambulance. Diagnosed with Pulmonary Embolism, and was operated on the next day and put on Blood thinner, Eliquos. Happened 20 days after THE VACCINE WAS GIVEN, and I almost died.

COVID19 VACCINE	JANSSEN	1201967-1	30-39 years	15-30 days	36 y.o. female referred for the above chief complaint. She has no significant medical history and presented with a headache that became severe 3 days ago. She received the Johnson and Johnson COVID vaccine on March 25th and had a mild headache following that which she attributed to the vaccine. 3 days ago the pain became excruciating and was associated with vomiting. This prompted presentation to the ED where she was treated with Dilaudid. She was discharged home and has been using her mom's headache cocktail with some transient relief. She presented back to the ED today with continued symptoms. MRV revealed a venous sinus thrombosis and neurology was therefore consulted. She has no history of clots personally or in the family. Her dad did have a stroke in his 50s. Patient otherwise denies any other associated speech change, vision change, extremity numbness, extremity weakness, coordination difficulty, or dizziness. Patient admitted to the neurology ICU and started on anticoagulation.
COVID19 VACCINE	JANSSEN	1202210-1	65+ years	15-30 days	DVT, pain and redness in ankle.
COVID19 VACCINE	JANSSEN	1202689-1	40-49 years	15-30 days	PATIENT REPORTS COUGHING UP BLOOD CLOTS FOR THE PAST 3 DAYS AND SENT PICTURE OF 1 THAT WAS COUGHED UP
COVID19 VACCINE	JANSSEN	1202699-1	40-49 years	15-30 days	Pain in ankle. Later diagnosed as DVT. Prescribed blood thinners
COVID19 VACCINE	JANSSEN	1203288-1	65+ years	15-30 days	pt developed a blood clot in his ear and sought treatment 9 d after vaccination
COVID19 VACCINE	JANSSEN	1203308-1	65+ years	15-30 days	Acute metabolic encephalopathy, BPH with urinary obstruction due to blood clot. Patient was vaccinated at a pharmacy with Janssen covid-19 vaccine and experienced headaches and dizziness. Then began to have urinary retention which was believed to be due to a large blood clot requiring 12x 100mL flushes. Patient went to ED at medical center on 3/30/21 and was admitted. He was discharged to nursing home on 4/11/21.
COVID19 VACCINE	JANSSEN	1203382-1	65+ years	15-30 days	Patient presented on April 1st, 2021 with COVID 19 pneumonia, B/L Pulmonary emboli and bilateral lower extremity DVT's. She was treated with heparin and warfarin for VTE. For COVID pneumonia, patient was treated with steroids, remdecivir and actemra.
COVID19 VACCINE	JANSSEN	1203501-1	50-59 years	15-30 days	Blood clots in kidney. Currently hospitalized.
COVID19 VACCINE	JANSSEN	1203902-1	65+ years	15-30 days	Blood Clot which led to Pulmonary Embolism, Pneumonia, and death.
COVID19 VACCINE	JANSSEN	1204231-1	65+ years	15-30 days	Suffered from a stroke on 4/3/21 from a blood clot in his brain stem. Prior to vaccine he was healthy and 100% independent, still drove, did grocery shopping, yard work, etc. Now he cannot move his left side and was placed on hospice as he has lost his will to eat, drink, or live.
COVID19 VACCINE	JANSSEN	1205079-1	65+ years	15-30 days	Pt stated that approximately two weeks after vaccination she went to her physician office for an issue with her eye. Her eye was severely red. At the physician's office, the physician told the patient that there was a small blood clot in her eye. The patient stated she didn't think anything of it at the time, but now that the CDC came out with the statement about the Janssen vaccination, she decided to report to the pharmacy.
COVID19 VACCINE	JANSSEN	1205819-1	40-49 years	15-30 days	Had chest pain on and off for 5 days (started Thursday 3/25), which I thought was related to acid reflux. On Tuesday 3/30 when it became worse and was no longer managed with ibuprofen I went to patient 1st. I was given an ekg which was abnormal and then sent to ER. There it was determined that I had a blood clot and 100% blockage in my right coronary artery. That night I had surgery and they placed a stent.
COVID19 VACCINE	JANSSEN	1206018-1	50-59 years	15-30 days	I had a blood clot in my left lung. went to ER, spent three days in the hospital was given medications (Xarelto) required to taking medication now for a least a year.
COVID19 VACCINE	JANSSEN	1206024-1	60-64 years	15-30 days	stroke caused by 2 cerebral blood clots
COVID19 VACCINE	JANSSEN	1206203-1	40-49 years	15-30 days	PATIENT SEEN FOR SOB X 2-3 WEEKS IN ED, CT SCAN SHOWED MULTIPLE PULMONARY EMBOLI. HEMODYNAMICALLY STABLE WITH NO EVIDENCE OF HEART STRAIN, D/C HOME ON XARELTO
COVID19 VACCINE	JANSSEN	1206334-1	50-59 years	15-30 days	Redness at site. On April 5, I had severe stomach pains and then a head ache started. They did a CT Scan and found a Portal Deep Vein Thrombosis. I had to be rushed by ambulance to a bigger hospital and was in the hospital for 2 days.
COVID19 VACCINE	JANSSEN	1207958-1	60-64 years	15-30 days	Cerebrovascular thrombus, with partial loss of sight. Numbness of the left arm
COVID19 VACCINE	JANSSEN	1208205-1	65+ years	15-30 days	deep vein thrombosis, swelling, pain in both legs and lower abdomen. warm and red skin. red swollen veins.
COVID19 VACCINE	JANSSEN	1208406-1	65+ years	15-30 days	received j&j vaccine on 3/11; dx w/ DVT on 3/26.

COVID19 VACCINE	JANSEN	1208463-1	40-49 years	15-30 days	I had horrible pain in my left calf that travelled to my thigh. I went to the hospital 2 weeks later and found that I have a blood clot in my lower leg (front ankle area). I am on blood thinners and will be seeing a Hematologist.
COVID19 VACCINE	JANSEN	1208701-1	65+ years	15-30 days	Migraines, lung infection, blood clots, pain in lungs, shortness of breath.
COVID19 VACCINE	JANSEN	1208778-1	50-59 years	15-30 days	patient has bilateral pulmonary embolism
COVID19 VACCINE	JANSEN	1209104-1	65+ years	15-30 days	3 weeks post vaccination patient developed chest pain and shortness of breath. Was able to tolerate symptoms, then had radiation treatment and developed more shortness of breath. Was transported via EMS to hospital where an xray and MRI were completed and showed multiple blood clots in her lungs. Venous Doppler was also completed and blood clots were found in her legs. She was subsequently admitted to hospital.
COVID19 VACCINE	JANSEN	1209277-1	65+ years	15-30 days	Received Janssen Vaccine on 03/10/2021 IM Left Deltoid. Reported started having "dizzy spells a couple weeks after" receiving his vaccination. Reports then started having "leg heaviness". Was hospitalized with hospital on 04/11/2021 with a blood clot "behind right knee".
COVID19 VACCINE	JANSEN	1209426-1	30-39 years	15-30 days	Janssen COVID-19 Vaccine EUA Patient presented to ED on 4/2/2021 with complaints of "worst headache of my life", waking her up at 2 am on 4/1/2021. Describes the headache as being 10/10, sharp, and located at the back of her head. Associated fevers of 101.2F, chills, generalized weakness and dizziness. The patient states she took ibuprofen with mild improvement of her symptoms, so called her PCP and had a CT head done. The patient states she received a call from her PCP prior to arrival stating to go to the closest emergency department because her CT head showed an acute cerebellar hemorrhage. Patient admitted to Medical Center. Cerebral angio performed on 4/5/2021 which demonstrated dural sinus thrombus. Platelet count 255 on 4/2/2021 (Range 193 - 255 from April 5th through April 14th).
COVID19 VACCINE	JANSEN	1209534-1	65+ years	15-30 days	J&J vaccine 3/15 and on 4/2/2021 I thought I pulled a muscle and my leg started swelling, but my right leg only. I thought it would go down and my leg and foot started swelling up and my foot got really cold. I went to the hospital on 4/11 and they said it was a DVT and they checked my lungs and said I had small blood clots in my lungs as well. They put me on Eliquis to keep my blood thinned out.
COVID19 VACCINE	JANSEN	1209619-1	65+ years	15-30 days	Starting on the 8th, I saw signs of blood in urine. It started being extensive and frequent. By Wednesday at 11:30 I had extremely red bloody urine with small clots. I went to (on Wednesday) Hospital ER - they performed a handheld exam - Flomax - to see if I could expel clotting. Late afternoon the next morning, I started expelling clots in very large quantities in very large clots. It got so bad that I had my wife take me to ER but we were in the parking lot and we called the Urologist - and he said that was what it was aiming for so that it would stretch the Urethra to pass the clots. So I didn't go to the ER. That night my urine began clearing. It stayed clear until early morning. I had a little blood and then it went away again. Since Friday, after I saw my Primary care doctor, I haven't had any blood in my urine. but I did see the doctor the next morning. I will see the Urologist tomorrow.
COVID19 VACCINE	JANSEN	1210220-1	40-49 years	15-30 days	achiness, slight fever, shortness of breath, pulmonary embolisms
COVID19 VACCINE	JANSEN	1210557-1	40-49 years	15-30 days	Pt states that she experienced low back pain and extreme fatigue after imz but resolved in 24 hours. On Sunday, (4/11/21) which is roughly 3 weeks later pt noticed pain in lower right leg (calf) which was warm and tender to touch. Pt went to urgent care and was immediately sent to ER. Diagnosis was DVT in right lower leg. Pt was administered 2 shots of heparin injection in abdomen and discharged on Eliquis. Pt followed up with PCP on today 4/14/21 and was told to continue Eliquis and to follow up in 1 week for another ultrasound to ensure medication is working.
COVID19 VACCINE	JANSEN	1210586-1	65+ years	15-30 days	right pulmonary embolus heparin drip pain below right rib cage in hospital 23 hours feel better now
COVID19 VACCINE	JANSEN	1212127-1	18-29 years	15-30 days	Site: Pain at Injection Site-Mild, Systemic: Blood Disorder (diagnosed by MD)-Medium, Systemic: Dizziness / Lightheadness-Severe, Systemic: blood clots in stool-currently under care of primary care physician for clot formation investigation-Medium, Systemic: Flushed / Sweating-Medium, Systemic: Headache-Medium, Systemic: Nausea-Medium, Systemic: Shakiness-Medium, Systemic: Unable to Sleep-Medium, Systemic: Weakness-Medium, Additional Details: patient reported blood clots in stool on 4/11/21 and 4/12/21. Patient was flushed, dizzy and faint after clot was found. Patient has no significant history of hemorrhoids or colorectal conditions.
COVID19 VACCINE	JANSEN	1212423-1	65+ years	15-30 days	Respiratory distress, sent resident to Emergency room ; CT scan done showed a small Pulmonary Embolism.

COVID19 VACCINE	JANSEN	1212435-1	65+ years	15-30 days	He got the vaccine, was not able to breath real good and didn't think about it. It got to the point within 2 weeks that he was not able to get up from the chair due to the shortness of breath. By 4/1/21 he was not able to breath very well, but continued to stay home. Then by 4/12/21 he was not able to breath well at all and his wife took him to the ER. In the hospital they did x-rays and found out that his lungs are full of blood clots and both legs have blood clots in them. He was admitted and gave him Heparin drip for the 2 days to get the blood clots dissolved and was also on oxygen for 2 days. He was discharged home yesterday with Xarelto, and was told that he would be on that for the rest of his life, and is on oxygen for sleep and when he's up and around, but if he's resting and feels he's breathing okay he can remove it. They informed him that it would take approximately 2 months for all the blood clots to dissipate, and that he was full of blood clots, and had both legs and both lungs which are quite full.
COVID19 VACCINE	JANSEN	1212726-1	60-64 years	15-30 days	Received vaccine 3/6/21, had Right Hip replacement surgery on 3/23/21 and had arterial blood clot post surgery with revascularization. Surgery performed by Dr. at a Medical Center
COVID19 VACCINE	JANSEN	1213007-1	65+ years	15-30 days	DVT of left popliteal vein per Venous US 4/14/21
COVID19 VACCINE	JANSEN	1213066-1	60-64 years	15-30 days	Patient presented with with on going shortness of breath. Patient was swabbed and diagnosed with COVID-19. CT of the chest shows that the patient had bilateral pulmonary emboli. Patient is currently being treated at our hospital for COVID-19 and PE
COVID19 VACCINE	JANSEN	1213131-1	65+ years	15-30 days	PATIENT DIED FROM BLOOD CLOT 3/29/2021 - AUTOPSY PERFORMED AND CONFIRMED
COVID19 VACCINE	JANSEN	1213399-1	65+ years	15-30 days	On April 11, 2021, patient passed a sizeable blood clot and has experienced labored breathing.
COVID19 VACCINE	JANSEN	1213473-1	50-59 years	15-30 days	right lower extremity femoral dvt
COVID19 VACCINE	JANSEN	1213979-1	40-49 years	15-30 days	HOSPITALIZED FOR BLOOD CLOTS, UNRESPONSIVE AND TAKEN TO HOSPITAL
COVID19 VACCINE	JANSEN	1214030-1	50-59 years	15-30 days	thrombosis of superficial vein of lower limb
COVID19 VACCINE	JANSEN	1214295-1	60-64 years	15-30 days	blood clot in arm
COVID19 VACCINE	JANSEN	1214297-1	60-64 years	15-30 days	patient was diagnosed with bilateral pulmonary emboli within 3 weeks of vaccine administration, developed dry cough within 1 week of vaccine that progressed to worsening shortness of breath.
COVID19 VACCINE	JANSEN	1214484-1	30-39 years	15-30 days	35yo G2P2 s/p term spontaneous vaginal delivery @ 38 wks gestation. On postpartum day #2, complained of pain and palpable varicosity behind lateral left knee. Doppler studies revealed superficial venous thrombosis, no DVT. Patient discharged on postpartum day #2 on prophylactic Lovenox daily. Patient Rh-negative - received Rhogam 1/22/21 during pregnancy and again after delivery. Otherwise, had no maternal complications this pregnancy. After the fact, pt notes that she has a sister with a history of unprovoked DVT in the past.
COVID19 VACCINE	JANSEN	1214697-1	65+ years	15-30 days	Janssen COVID-19 Vaccine EUA Patient received J&J COVID Vaccine on 3/15/2021 per vaccine card. Patient had an ED Visit on 3/17/2021 for a chief complaint of lightheadedness and was diagnosed with Pneumonia with Chest X-ray showing small bilateral pleural effusions with underlying atelectasis or consolidation. On 4/12/2021, Patient presented to ED as instructed by outside physician for finding of blood clot on CT the morning of 4/12/2021 (Pulmonary emboli at the left upper lobe). The patient had CT scheduled during an office appointment on 4/5/2021. Patient admitted for treatment of pulmonary embolism.
COVID19 VACCINE	JANSEN	1215369-1	50-59 years	15-30 days	DVT right lower extremity and pulmonary embolism: was hospitalized for 2days with a Heparin Drip and discharged home with Eliquis 10mg twice a day. Home meds discontinued: all BP meds, Ibuprofen, Tylenol, and Torodol. Follow up appointments with Dr. oncologist. Also had to cancel upcoming ventral hernia repair after having to wait 3 years due to complications with bowel obstructions and had to lose weight before surgery due to high risk. Now will have to wait longer until cleared medically, primary physician instructed me that it would be 6months or more before being cleared.
COVID19 VACCINE	JANSEN	1215800-1	40-49 years	15-30 days	High fever for 3 days, lost of taste. Stomach pains and heavy menstrual cramps and bleeding. Blood cloths while menstrual cycle.
COVID19 VACCINE	JANSEN	1218425-1	50-59 years	15-30 days	Patient received the COVID 19 vaccine on March 18, 2021 @6:00pm. On April 5, 2021 @8:00am the patient began to feel pain in L leg which progressed to area red and tender to touch and increased in pain with each day. Patient went to the ER on April 9, 2021 and an ultrasound revealed a 10 cm blood clot in left leg. Patient was not admitted but sent home on Zarelto 15 mg 2x daily. Patient did see physician as a follow up.

COVID19 VACCINE	JANSSEN	1218748-1	65+ years	15-30 days	74-year-old female with cardiac risk factors presents with exertional dyspnea over the past 3 days. Patient had low oxygen saturation 81% at the doctor's office which came up to 89 with rest. Patient placed on oxygen here in the emergency department. Patient does not have symptoms at rest. Patient does not have any calf swelling or pleuritic pain. Patient's D-dimer is elevated therefore CT angio of the chest was obtained which shows large, central pulmonary embolism with evidence of right heart strain.
COVID19 VACCINE	JANSSEN	1218885-1	40-49 years	15-30 days	The patient claims to have received the J and J vaccine on 3/30. He also claims it was his ""second shot"". He says he has felt ill since this shot, had an admission to the hospital and discharge for CHF. On 4/15, admitted again with Bilateral pulmonary emboli. He says the only thing he has done differently is vaccine. ""
COVID19 VACCINE	JANSSEN	1218928-1	40-49 years	15-30 days	Left upper arm superficial thrombophlebitis
COVID19 VACCINE	JANSSEN	1219810-1	50-59 years	15-30 days	Patient received his J&J vaccine on 3/19/21 at at outside location. Patient was admitted to the hospital for acute urinary retention on 4/7/21 and had a catheter placed via cystoscopy. He was discharged on 4/8/21. On 4/14/21 he presented to the ED with chest pressure/palpitations/dizziness. He stated that he has had chest pressure for 1 week prior to the this. CT revealed a saddle pulmonary embolism. he was admitted to the hospital for further work-up and treatment.
COVID19 VACCINE	JANSSEN	1219954-1	65+ years	15-30 days	Day of vaccine I didn't feel bad, just felt queasy later, I was tired the next day. I don't know when the SOB started but it continued through the month of March. I thought it was an exacerbation of my chronic issues, by Sunday 4/4/20221 I coughed up blood, and on Monday I went to the hospital and had a CT scan and was told I had a pulmonary embolism and a clot in my leg. Now I'm on an injectable blood thinner for the rest of my life and I was told it would take 3-4 months to resolve the blood clots.
COVID19 VACCINE	JANSSEN	1223028-1	40-49 years	15-30 days	Seemed to very much effect my menstruation. My period came 10 days late, then this month?s period was 2 weeks early. Very bad clotting with menstrual bleeding. I am normally very regular so this was extremely unusual.
COVID19 VACCINE	JANSSEN	1223212-1	40-49 years	15-30 days	03/24/2021 Blood clot appeared on left arm area of mid forearm. Blood clot raised skin and was painful to touch. Treated with hot pack for approximately 20 min. Blood clot remained for approximately 8 hours and then broke the vein and I was bruised for approximately 5 days.
COVID19 VACCINE	JANSSEN	1223495-1	30-39 years	15-30 days	I was 9 months pregnant at the time of the vaccination. My due date was April 3, 2021. The actual date of delivery was March 20, 2021 by C-section. I gave birth to a son weighing 8 lbs 6 oz. I had no complications during this pregnancy. I left the hospital on March 22nd. On March 25, I was experiencing shortness of breath and a low pulse (35 bpm; my usual pulse is in the 50s-60s). My OBGYN told me to go to the emergency room, where they did a CT scan. The CT scan showed a small pulmonary embolism. I was in the hospital until March 27th, where I was treated with Heparin and then was released with Lovenox injections. I am currently on the Lovenox. After seeing the pulmonologist for a follow-up appointment, he advised me that I would be able to stop the injections after 3 months.
COVID19 VACCINE	JANSSEN	1225302-1	40-49 years	15-30 days	Submassive pulmonary embolism leading to shortness of breahrt
COVID19 VACCINE	JANSSEN	1225587-1	40-49 years	15-30 days	Pt found to have bilateral subsegmental pulmonary emboli. No right heart strain. Otherwise determined to be low-risk PE but will require anticoagulation.
COVID19 VACCINE	JANSSEN	1225900-1	30-39 years	15-30 days	Patient with large pulmonary embolism. Associated thrombocytopenia. No provoking factor identified.
COVID19 VACCINE	JANSSEN	1228271-1	30-39 years	15-30 days	Patient has been having left arm pain. Developed acute, partially occlusive left subclavian deep vein thrombosis found on duplex on 4/16/21. She was started on lovenox and will have further work-up.
COVID19 VACCINE	JANSSEN	1228668-1	65+ years	15-30 days	My symptoms i had sever headache! Once April 1st Hit! Thats Was the day I Had a Heart stroke at store, i don?t remember anything and once i woke up i was at the hospital, and they told me that i had a heart stroke because i had lots of blood clots in my body. And they told me i vomit and peed myself during the whole situation i went in store
COVID19 VACCINE	JANSSEN	1228936-1	65+ years	15-30 days	Patient developed chest pain and shortness of breath 4/15 Presented to hospital emergency department 4/17 found to have a pulmonary embolism without heart strain, however with pulmonary infarction of left lower lobe with associated right lower extremity DVT Patient admitted to the hospital, initiated on therapeutic anticoagulation with Lovenox, started on oxygen therapy for acute hypoxic respiratory failure Discharged home 4/20 on therapeutic anticoagulation with Xarelto and home oxygen as needed

COVID19 VACCINE	JANSSEN	1229724-1	60-64 years	15-30 days	Patient started with Left lower leg pain and redness on 4.1.21. Went to Emergency dept on 4.4.21 and diagnosis of Left leg cellulitis and prescribed Doxycycline. Patient came to PCP office on 4.6.21 with worsening left lower leg pain and swelling. Order L lower leg doppler. Diagnosis of L lower leg deep vein thrombosis of tibial vein on 4.7.21 and prescribed Apixaban 5mg 2 BID x 7 days on 4.7.21
COVID19 VACCINE	JANSSEN	1229731-1	50-59 years	15-30 days	Extreme pain in legs & feet Pain in chest with deep breaths
COVID19 VACCINE	JANSSEN	1230406-1	65+ years	15-30 days	On 4/9/2021 started with left sided pleuritic CP and went to ED and found to have bilateral pulmonary emboli. On Eliquis 5mg BID No underlying chronic conditions for increased risk of PE Extensive work up without a direct cause found, no underlying malignancy noted
COVID19 VACCINE	JANSSEN	1230498-1	50-59 years	15-30 days	DVT
COVID19 VACCINE	JANSSEN	1230519-1	50-59 years	15-30 days	Healthy, active menopausal woman on estrogen containing hormone replacement therapy developed posterior knee and upper leg pain was found to have a RLE DVT 4 weeks after the J and J vaccine without any other inciting events or risk factors.
COVID19 VACCINE	JANSSEN	1230521-1	50-59 years	15-30 days	Healthy, active menopausal woman on estrogen containing hormone replacement therapy developed posterior knee and upper leg pain was found to have a RLE DVT 4 weeks after the J and J vaccine without any other inciting events or risk factors.
COVID19 VACCINE	JANSSEN	1230877-1	60-64 years	15-30 days	patient came to clinic c/o right lower leg swelling on 4/6/2021, on 4/13/2021 she underwent a doppler us and was dx with right common femoral vein thrombus. her platelets are normal
COVID19 VACCINE	JANSSEN	1231406-1	50-59 years	15-30 days	About 3 weeks after the vaccine I started having severe chest and belly aches on the right side. CT scan showed a blood clot on my lungs and pneumonia
COVID19 VACCINE	JANSSEN	1231692-1	18-29 years	15-30 days	5 Blood clots coming from right nostril, headache, fatigue, stomach pains Nose bleed with clots lasted 15-20 minutes. Headache, fatigue, stomach pains lasted throughout the day.
COVID19 VACCINE	JANSSEN	1232051-1	30-39 years	15-30 days	Received J+J Covid vaccine on 4/3/21. Admitted on 4/19. Per admission note: Patient is a 36YO male with a history of HFrEF s/p heartware 12/17/14, ICM with embolic MI, CAD, chronic driveline infection, HTN, HLD, DM type II, SVT, obesity, gout who was sent to the hospital for bilateral PEs. Patient called our OP line on 04/17 complaining of fever of 102 and chills. He was instructed to go to local lab and get labs done. They drew basic labs as well as blood cultures. On Sunday, the patient reported his fever was gone and he felt better. Today, he was feeling SOB and presented to his PCP. They ordered a CTA which reportedly showed bilateral PEs. They sent him to the local ED who transferred him here. Of note, his INR has been supratherapeutic for several weeks and pharmacy has been adjusting his warfarin dosing. The patient tested COVID negative prior to transfer. The vaccine lot number information is not accessible to this reporter.
COVID19 VACCINE	JANSSEN	1232289-1	65+ years	15-30 days	right lung PE
COVID19 VACCINE	JANSSEN	1232476-1	50-59 years	15-30 days	Patient presented to Emergency Department on 4/17/21 with a severe headache that started 5-7 days prior. CBC and Chem-8 were normal with platelets of 314. Findings from CT head venogram showed irregularities of the left transverse sinus with possible sinus thrombosis. Patient was admitted for further work-up and treatment. Patient was followed by Neurology. On 4/18 MRI revealed no cavernoma seen and no stroke or hemorrhage. Per Neurology, the areas of filling defects seen on CTV are still present which could be nonocclusive thrombus vs stenosis with prominent arachnoid granulations, but given history and risk factors, would treat as cerebral sinus venous thrombosis. Patient was treated with heparin then transitioned to apixaban, which she was discharged on. Patient was instructed to follow up with neurology in 3 months for a repeat CTV. Patient was discharged 4/19/21.
COVID19 VACCINE	JANSSEN	1232593-1	50-59 years	15-30 days	pulmonary embolism and CVA suffered approximately 2 weeks post vaccination
COVID19 VACCINE	JANSSEN	1233202-1	50-59 years	15-30 days	Patient states that while vacationing, 3 weeks and 1 day after receiving her Janssen vaccine, she woke up at 8:30am with numbness in her left foot. When attempting to stand she fell to floor. After checking her blood pressure and blood sugar she took 2 tylenol and sat down to rest. Around 10:30am she began to have numbness in her left hand and on the left side of her face. She was taken by ambulance at that time to Hospital. While there they ran a number of tests and scans diagnosing her with have a stroke caused by a small blood clot in right side of her brain. She was admitted to the hospital and was not discharged until 4/3/2021. Upon returning home, she has been seeing her PCP, APRN and a neurologist. She has since been released on 4/19/2021 to go back to work and has no residual side effects from stroke. She states she is now on blood pressure and cholesterol medication and is taking a daily baby Aspirin.

COVID19 VACCINE	JANSEN	1233912-1	65+ years	15-30 days	Intermediate Risk PE-diagnosed due to symptoms of pre-syncope, palpitations. Clinical history includes long car ride
COVID19 VACCINE	JANSEN	1234059-1	50-59 years	15-30 days	Less than 1 mo following injection pt developed DVT RLE. He presented with rt foot/ankle pain 3/29. The pain improved then around 4/10 he developed significant pain/swelling to rt calf. Venous US confirmed DVT. Pt started on Eliquis. Pt has h/o superficial thrombosis, not h/o DVT.
COVID19 VACCINE	JANSEN	1234286-1	40-49 years	15-30 days	pt said she had isolated pain above her left elbow around 4/13/2021. the pain is now from her elbow to mid bi-cep. (she had given blood on 3/4/2021) pt saw a provider on 4/19/2021 regarding her symptoms. She was referred for a US. Results were superficial thrombosis left cephalic vein at the level of the mid upper arm extending into the forearm. She had blood work and was told to take Ibuprofen for pain and to stop taking her birth control. Pt will have a FU appt to discuss blood work results.
COVID19 VACCINE	JANSEN	1234500-1	30-39 years	15-30 days	Blood clot leading to stroke
COVID19 VACCINE	JANSEN	1234526-1	60-64 years	15-30 days	Blood clot in left leg on 3/22/2021 and 3/29/2021
COVID19 VACCINE	JANSEN	1235447-1	30-39 years	15-30 days	Patient presented to the ER on 4/20/21 with headache. On Saturday (4/17/2021), the patient had ""the worst headache I have ever had"" along with severe inner left ear pain. Patient took an ibuprofen which helped with the pain for about an hour then the pain came back. Pain got worse 2 hours later when she drove home from work. She called the RN line and was told to take ibuprofen and follow up in the AM. The next day 4/18/2021, patient went to urgent care and received Toradol and was told it was a migraine. Today 4/20/21, patient still had pain and noted feeling left sided facial numbness and blurry vision that correlated with when she got the headache. Patient went to an urgent care today and CT scan revealed a blood clot. She was then sent to the ED for evaluation. In the ED, she has no headache and facial numbness and has minimal left ear pain. Her headache is localized to the left side of her head. Patient denies fever, chills, and COVID symptoms. Patient was started on argatroban drip per hematology recommendation.""
COVID19 VACCINE	JANSEN	1235593-1	40-49 years	15-30 days	I received the Janssen vaccine on 3/5/2021. My first menstrual cycle after the vaccine, which started on 3/21/21, was significantly different than any other period. I woke in the middle of the night to extreme pain in my abdomen and bled along the floor as I walked to the bathroom. There were clots in the blood in addition to extraordinarily heavy blood flow. The period was so significantly different from any other that I scheduled an appointment with a nurse practitioner that works with my primary care doctor. I asked her to ""run"" all tests that were available and approved by insurance, which she did. All came back normal. Due to the significant difference in my period this month, the ARNP requested an inner-uterine ultrasound which found the below:""
COVID19 VACCINE	JANSEN	1236124-1	30-39 years	15-30 days	4 days of right upper extremity pain and swelling with diagnosis of right upper extremity axillary vein DVT that was treated with DOAC apixaban.
COVID19 VACCINE	JANSEN	1236823-1	60-64 years	15-30 days	patient received vaccine 3/24/21, presented to the hospital with pulmonary embolism
COVID19 VACCINE	JANSEN	1237164-1	60-64 years	15-30 days	PATIENT PRESENTED TO OUR EMERGENCY ROOM WITH COMPLAINTS OF DIZZINESS, VERTIGO, AND VOMITING WHICH ONSET WAS ONE DAY. PATIENT REPORTS RECEIVING JOHNSON & JOHNSON COVID VACCINE 2 WEEKS AGO . CTA OF HEAD SHOW POSSIBLE TRANSVERSE VENOUS SINUS THROMBOSIS ABOUT 7MM, PATIENT IS ADMITTED TO ICU FOR FURTHER WORK UP .
COVID19 VACCINE	JANSEN	1237348-1	50-59 years	15-30 days	Patient reports right hand severe swelling starting one week after Johnson and Johnson covid vaccine with pain in the hand. She went to ER and US showed a DVT in forearm. Patient was placed on aspirin and states the swelling has improved some but still has some swelling and pain.
COVID19 VACCINE	JANSEN	1237651-1	50-59 years	15-30 days	Possible cerebral venous sinus thrombosis
COVID19 VACCINE	JANSEN	1237704-1	Unknown	15-30 days	Death, blood clots in liver
COVID19 VACCINE	JANSEN	1238791-1	40-49 years	15-30 days	pulmonary embolism in left and right lungs- Day 17 after vaccine
COVID19 VACCINE	JANSEN	1238925-1	40-49 years	15-30 days	Pt experienced pain/cramping in his right leg on or about 4-15-21. Thought this was due to new work shoes. Pain continued through the weekend and on Monday 19th visited his PCP where a scan was preformed confirming a clot in his right leg between his thigh and ankle. Pt started on therapy and has a follow up with his physician on Friday 23rd. Pt doing well and in good spirits.

COVID19 VACCINE	JANSSEN	1239122-1	40-49 years	15-30 days	Chief complaint of worsening lower leg pain. Initially the patient thought that he had pulled a muscle however he had complaints of claudication upon ambulation. Patient reports having J&J COVID vaccination approx 2.5 weeks prior. Patient reported his friend informed him that he might potentially have a blood clot and that he should come to the emergency department. Imaging consistent with acute DVT and patient taken to IR for tPA direct catheter infusion.
COVID19 VACCINE	JANSSEN	1242233-1	30-39 years	15-30 days	Blood clots in the Liver and Kidney also Pulmonary Embolism. went to ER was admitted and spent 6 days there. was put on Heparin as well as antibiotics. currently on Warfarin to maintain proper blood INR numbers.
COVID19 VACCINE	JANSSEN	1242553-1	65+ years	15-30 days	"I received the Johnson and Johnson Covid vaccine on March 9th. On March 30 I was admitted to the hospital with excessive blood clots in my right leg and right lung. My Pulmonary Dr felt I should report this to you. I did have blood clots last year and recently ( February 8th) had back surgery both circumstances could of contributed to the issue. If you need any further information or have questions please do not hesitate to contact me.""
COVID19 VACCINE	JANSSEN	1243207-1	65+ years	15-30 days	pts granddaughter says she was not feeling well and a couple of weeks after taking the vax and had to call 911 on 4/16/2021. Paramedics took her to Hospital ER, in same city and state as patient, where she was admitted. She called her granddaughter 4/18/2021 and told her she had tested positive for Covid Virus while at the hospital and that she had a blood clot on her lung. She is being treated w/ a blood thinner.
COVID19 VACCINE	JANSSEN	1243888-1	30-39 years	15-30 days	Patient received the vaccine at her home. She was straight cathed by a home health nurse and there was a blood clot and a large amount of blood noted to her urine. She was monitored over the weekend, but her urine remained clear. She has been in her usual state of health and has had no other symptoms since then
COVID19 VACCINE	JANSSEN	1243963-1	40-49 years	15-30 days	Vaccine on 3/29 leg pain 4/14 DVT seen on U/S 4/18
COVID19 VACCINE	JANSSEN	1244004-1	50-59 years	15-30 days	Patient received the COVID 19 vaccine on 4/2, he developed symptoms of COVID on 4/10, he tested positive for COVID on 4/13. He was admitted to the hospital on 4/17 for acute respiratory failure. On 4/20, he was diagnosed with a pulmonary embolus.
COVID19 VACCINE	JANSSEN	1246172-1	65+ years	15-30 days	PATIENT EXPERIENCE A BLOOD CLOT IN LEG AND HAD TO BE HOSPITALIZED
COVID19 VACCINE	JANSSEN	1246385-1	50-59 years	15-30 days	Patient presented to ED on 4/22/2021 with non-productive cough, mild shortness of breath x 10 days. Acute onset chest pain x 1 day. Chronic bilateral leg swelling, but worsening leg pain. Hx of DVT and PE, not on anti-coagulation.
COVID19 VACCINE	JANSSEN	1246654-1	65+ years	15-30 days	admitted to University of South Alabama Medical Center on 4/20/21 with bilateral Pulmonary embolus
COVID19 VACCINE	JANSSEN	1246723-1	40-49 years	15-30 days	Patient reports receiving Johnson and Johnson COVID vaccine on 3/19/21. He was hospitalized on 4/6/21 for an acute pulmonary embolism.
COVID19 VACCINE	JANSSEN	1246817-1	50-59 years	15-30 days	Blood clot in each lung. Started in legs, spread through heart and settled in lungs. This occurred about 3 weeks AFTER J&J/Jansen vaccine. Immediate symptoms were painful leg cramps on both sides back pain, fever sweating, nausea, clammy skin, headache, neck pain.
COVID19 VACCINE	JANSSEN	1247654-1	30-39 years	15-30 days	Patient got the J&J Covid vaccine on 4/2/2021, presented to the ER on 4/20/2021 with complaint of left chest and shoulder pain. This has been progressively getting worse over the past 3 days. She denies any overt shortness of breath or cough and her vital signs are stable.
COVID19 VACCINE	JANSSEN	1248189-1	30-39 years	15-30 days	Blood clot in superficial vein in right heel of foot
COVID19 VACCINE	JANSSEN	1248245-1	18-29 years	15-30 days	Patient developed calf pain 4 days prior to her ER presentation on 4/22/2021. Found to have an occlusive DVT of the left posterior tibial vein.
COVID19 VACCINE	JANSSEN	1251068-1	60-64 years	15-30 days	PT STATED HE WENT TO THE CLINIC AND THEN THE ER WITH A BUMP ON THE BACK OF HIS LEG. PT WAS TOLD IT WAS A BLOOD CLOT.
COVID19 VACCINE	JANSSEN	1251445-1	65+ years	15-30 days	Feeling quite ill. Did not sleep night before trip to hospital. Terrible taste in mouth. Taken to hospital emergency room morning of April 18, 2021. Admitted to hospital by ER physician. Reason: blood clots in both lungs.

COVID19 VACCINE	JANSSEN	1251619-1	65+ years	15-30 days	At unspecified date the patient's nephew noticed acute onset change in the patient's mental status. Upon arrival to unspecified hospital by EMS she was aphasic with right facial droop, right gaze preference, right sided weakness. CT and CTA showed Intraparenchymal hemorrhage with 3mm midline shift as well as superior sagittal dural sinus thrombus in the anterior 3rd. Repeat NCHCT showed bilateral parenchymal hemorrhages.
COVID19 VACCINE	JANSSEN	1251686-1	65+ years	15-30 days	Admitted to hospital with Covid 19 infection, fever, pulmonary embolism
COVID19 VACCINE	JANSSEN	1252018-1	65+ years	15-30 days	On 4/16/2021 went to the emergency room with high blood pressure that was noted as a ""hypertensive emergency"". Was admitted into the hospital the next day where a CT scan confirmed that a blood clot in the brain occurred which led to a basal ganglia stroke. After a 5 day stay in the hospital, patient is now in a full time rehab facility to attempt to recover her cognitive and speech skills, while also attempting to regain use of her right hand which is currently not functioning due to the stroke.""
COVID19 VACCINE	JANSSEN	1255952-1	65+ years	15-30 days	Approximately 3.5 weeks after JANSSEN covid vaccine, patient developed an acute pulmonary embolism.
COVID19 VACCINE	JANSSEN	1256761-1	40-49 years	15-30 days	Janssen COVID-19 vaccine EUA Patient presented to hospital after crushing chest pain and syncopal event. Found to be hypotensive and hypoxic and echocardiogram revealed RV dilation and dysfunction with clot visualized in R atrium of heart. Patient received IV alteplase followed by start of IV heparin infusion. Currently intubated in ICU, on 3 vasopressors for shock.
COVID19 VACCINE	JANSSEN	1258458-1	60-64 years	15-30 days	2021-04-23 Patient presents to the ED with right-sided mid-back pain and shortness of breath starting 2021-04-22 evening. Pain is sharp and worsens with coughing and deep inspiration; she feels that she is taking shallow breaths. On ED presentation, no shortness of breath, chest pain, dizziness, fevers, dysuria, or abdominal pain. She does have reproducible pain on her right mid-back area. There is some mild diffuse tenderness in her abdomen, but reports that she always has a tender abdomen due to Crohn's disease. No peritoneal signs. No recent travel. Patient was found to have pulmonary embolism. Hematology/Oncology specialist was consulted and recommended initiation of argatroban for treatment of pulmonary embolism. Patient was admitted to inpatient.
COVID19 VACCINE	JANSSEN	1259526-1	50-59 years	15-30 days	Patient developed portal vein thrombosis and thrombocytopenia
COVID19 VACCINE	JANSSEN	1259560-1	50-59 years	15-30 days	ultrasound the left lower extremity shows extensive occlusive lower extremity DVT involving multiple veins. Labs otherwise unremarkable, patient appears well, denies chest pain or shortness of breath. He had the J+J vaccine less than 3 weeks ago.
COVID19 VACCINE	JANSSEN	1259681-1	65+ years	15-30 days	arm pain followed by shortness of breath 2 weeks later and pulmonary embolism
COVID19 VACCINE	JANSSEN	1260781-1	60-64 years	15-30 days	posterior tibial vein non-occlusive thrombus. RLE pain starting 4/23, diagnosed 4/26
COVID19 VACCINE	JANSSEN	1261867-1	50-59 years	15-30 days	Blood clots, heart attack, died, cpr 5 times survived Blood is very thick blood thinners unable to thin
COVID19 VACCINE	JANSSEN	1262195-1	60-64 years	15-30 days	Deep vein thrombosis
COVID19 VACCINE	JANSSEN	1262742-1	30-39 years	15-30 days	Patient received vaccine on 4/5/21. She presented to her PCP on 4/22 with swelling and redness in the inside upper area of her right arm. Determined to be a superficial thrombosis. Patient has not history of VTE, but does smoke. Uses a Mirena IUD for contraception as well. Platelet count remained normal during this time, and was never affected.
COVID19 VACCINE	JANSSEN	1262795-1	65+ years	15-30 days	Patient developed cough, fever, shortness of breath on 4/22/21. Tested positive for COVID-19 and was found to have a pulmonary embolus in the ER on 4/27/21. She is currently admitted at Hospital, under my care. I'm also her primary care physician.
COVID19 VACCINE	JANSSEN	1262924-1	65+ years	15-30 days	Patient received J&J vaccine 3/30/21 4/21/21 Presented to hospital with syncope and collapse, work-up for NSTEMI and placed on heparin infusion Patient found to have RLE DVT and bilateral PE with right heart strain. Platelet decreased and patient started on argatroban infusion. HIT negative, platelets remained stable. Discharged 4/25/21 on apixaban
COVID19 VACCINE	JANSSEN	1263266-1	50-59 years	15-30 days	Pulmonary embolism, Deep vein thrombosis - treating with Eliquis
COVID19 VACCINE	JANSSEN	1263446-1	60-64 years	15-30 days	Patient developed life threatening thromboembolism ( PEs) which potentially could have been caused by the Janssen vaccine
COVID19 VACCINE	JANSSEN	1263497-1	40-49 years	15-30 days	Blood clot, L arm (where pic line was located)

COVID19 VACCINE	JANSEN	1263525-1	60-64 years	15-30 days	Left leg pain started about 4/16/21. Reports evaluated by nurse practitioner at the medical office of primary care provider on 4/23/21. Ultrasound ordered a hospital and diagnosed with a blood clot in the left leg on 4/23/2021. Placed on a ""blood thinner"" to take orally BID for one month then once daily for undetermined duration. States MD is not considering the vaccination as the reason for the blood clot because of the duration of time between when the vaccine was given and the onset of the blood clot. When asked, pt reports a platelet count was done.""
COVID19 VACCINE	JANSEN	1264000-1	65+ years	15-30 days	My sister suffered a massive stroke with blood clots. Totally paralyzed on right side and limited speech. Unable to function on her own, receiving care at a Nursing Home
COVID19 VACCINE	JANSEN	1264082-1	65+ years	15-30 days	The pt said she developed a blood clot on her posterior hand. I asked her if it was a bruise on the back of her hand and she said it was a blood clot. She said she slapped the bump/clot and it subsequently went down/away.
COVID19 VACCINE	JANSEN	1264375-1	60-64 years	15-30 days	Headache, leg swelling Sent to ED for evaluation blood clot in leg
COVID19 VACCINE	JANSEN	1265131-1	65+ years	15-30 days	Pulmonary Embolism RLL Dyspnea and RUQ pain started @ 6 days prior (4/8/2021) to hospital admission on 4/14/2021. Went to hospital secondary to n/v/RUQ pain and was found to have choledocholithiasis. Due to dyspnea, CTA was performed with positive PE. PE was felt to be present on admission. Of note, patient was also found to have a lung mass on the Left upper lobe. Mass has grown from prior CT scans and is considered suspicious. Plan for pulmonology f/u and PET scan is pending.
COVID19 VACCINE	JANSEN	1266091-1	30-39 years	15-30 days	Patient received COVID J&J vaccine on 4/6, Presented to ED on 4/27/21 with complaint of 3 days of increasing leg pain and SOB
COVID19 VACCINE	JANSEN	1266356-1	60-64 years	15-30 days	For the past 2 1/2 - 3 weeks I have had a pain in my left leg. Today it was extremely painful so I went into the dr. office and after an examination and ultra sound it was determined that I have a blood clot.
COVID19 VACCINE	JANSEN	1266422-1	65+ years	15-30 days	Patient stated that her doctor says she has blood clots and believe it could be due to the vaccine.
COVID19 VACCINE	JANSEN	1266733-1	50-59 years	15-30 days	Patient reported left calf pain on 4/6/2021. She underwent lower extremity duplex which was positive for left deep vein thrombosis.
COVID19 VACCINE	JANSEN	1266856-1	65+ years	15-30 days	On 04.23.2021, developed leg swelling and was diagnosed with Right lower DVT. Was not admitted to the hospital. Was give RX for Eliquis
COVID19 VACCINE	JANSEN	1266881-1	60-64 years	15-30 days	Patient admitted for acute pulmonary embolism. Patient does not have thrombocytopenia.
COVID19 VACCINE	JANSEN	1267017-1	50-59 years	15-30 days	Entire leg red, swollen, 4+ edema from hip to toes.
COVID19 VACCINE	JANSEN	1267199-1	65+ years	15-30 days	patient developed severe chest pain, ambulance was called and patient was taken to ER. Patient was transferred to higher level facility and was told he had a heart attack and that it was caused by a ""blood clot""""
COVID19 VACCINE	JANSEN	1268576-1	40-49 years	15-30 days	A 40 year old man with no apparent risk factors for current disease presents with an anterior myocardial infarction. At acute in far related angioplasty is LAD is found to be completely included by fresh red clot that was removed using an instruction catheter. Imaging of the interior endothelial surface of the left anterior descending which was occluded by clot did not reveal any ruptured plaque or abnormality in the endothelium. He experience extensive anterior myocardial infarction and now has a left ventricular ejection fraction between 35 and 40%. This was an and usual presentation in a young man who appears to be fit with no family history of cardiac disease. A non-smoker. Normal lipid profile. The nature the invite itself was unusual in that no abnormality of the vessel that was occluded by fresh thrombus could be detected
COVID19 VACCINE	JANSEN	1268686-1	60-64 years	15-30 days	Flu-like symptoms chills fever up and down shortness of breath itchy skin dry cough shaky hands restless urinating frequently urination blood clotting in calves
COVID19 VACCINE	JANSEN	1270139-1	30-39 years	15-30 days	Started experiencing extreme chest pains (stabbing feeling) between my lower right breast and upper rib cage on Saturday afternoon, especially when trying to take a big inhale. I went to the emergency room the next day after pain meds (ibuprofen) did not help, and they did an EKG and X-Ray and they said it was a muscle strain. I went home and alternated between 3000 MGs of Tylenol every 24 hours, 2400 MGs of Ibuprofen, 8 hours of 4% lidocaine patch and then off for 8 hours + and a heating pad when the patch was off. The pain in my chest got worse and worse on Mon and Tue (started having spasms in the chest that caused extreme sharp shooting pain down my back up into my head) so went back into the ER Tues night. They

COVID19 VACCINE	JANSEN	1270168-1	40-49 years	15-30 days	Cerebral vein thrombosis - saggital sinus, right sigmoid and trasnverse extending to right jugular vein thrombocytopenia SAH bilateral frontal sulci
COVID19 VACCINE	JANSEN	1270602-1	60-64 years	15-30 days	shortness of breath
COVID19 VACCINE	JANSEN	1270699-1	50-59 years	15-30 days	superficial blood clot in right leg
COVID19 VACCINE	JANSEN	1271429-1	50-59 years	15-30 days	Patient developed acute dyspnea with exertion 04/27. Went to hospital ED, found to have acute hypoxic respiratory failure. CT-PE showing submassive saddle pulmonary embolism with several large emboli in bilateral upper and lower pulmonary arteries. Transferred from outside hospital to another Hospital. Started on IV Heparin infusion with transition to Enoxaparin. Had significant drop in platelet count and developed peripheral thrombi in all extremities. Concerned for HIT at that time, and review of CDC recommendations for COVID vaccine-associated thrombi, patient transitioned to Fondaparinux and remains on at present.
COVID19 VACCINE	JANSEN	1271930-1	50-59 years	15-30 days	starting have shortness of breath/difficulty breathing and back and chest pain. light headed, pain unbearable. Saturday April 23rd Went to er was treated for kidney stones but they could only find one small one, Was sent home with pain medication. Shortness of breath persisted as did bloody cough and pain in chest and all over. Went back to the er on 4/28 as pain was unbearable (chest pain) once given a cat scan and diagnosed with blood clots in my lungs and then an ultra sound and found a blood clot in my leg (just above knee). It is thought that I was mis-diagnosed on the original trip to the er with kidney stones. I have been put on blood thinners and pain medication and will be following up with my doctor.
COVID19 VACCINE	JANSEN	1271991-1	40-49 years	15-30 days	Patient is a 46 year old female who was admitted on 4/27/2021 for ACUTE DVT, UNSPECIFIED VEIN. 46 year old female with past medical history of POTS and on chronic hormonal oral contraceptive medication, and reported history of recurrent renal stones. Patient presented to ED after several days of left upper quadrant pain and tenderness, that worsened and became associated with nausea and vomiting. Initial evaluation by imaging demonstrated left renal stone in left renal pelvis with associated mild hydronephrosis. Incidentally on imaging, patient had DVT noted in right illiac vein with continuation into IVC. Subsequently admitted and started on heparin drip and pain control.
COVID19 VACCINE	JANSEN	1272424-1	40-49 years	15-30 days	48yoM (h/o childhood asthma, GERD, lipomas, preDM, obesity BMI 30) who had Covid J&J vaccine 3/12/21, then 4/4/21 had dizziness and a little SOB, seen in ER with neg brain MRI/MRA and trop/EKG neg. and labs. Later had DDIMER 560 on 4/15/21 due to h/o J&J vaccine and CTA lung 4/29/2021 shows Right lower lobe pulmonary emboli. Patient is clinically much better. No more SOB. Dizziness a little residual but significantly better. Never had hypoxia/tachycardia and BP always reassuring. Pt read about some blood thinner making clot worse and doesn't want to to start a blood thinner without checking with hematology first. I've prescribed rivaroxaban so that pharmacy can start authorization and ensure coverage, but patient strongly states that he will not take it yet until hearing from hematology.
COVID19 VACCINE	JANSEN	1272661-1	65+ years	15-30 days	Acute DVT
COVID19 VACCINE	JANSEN	1272711-1	65+ years	15-30 days	initially had mild headache and diarrhea but this resolved after a few days. Then around 4/25, developed atraumatic bruising and swelling and pain to the left biceps region (opposite side from vaccine). denied current headache/visual symptoms/abdominal pain or other bleeding/bruising.
COVID19 VACCINE	JANSEN	1273017-1	30-39 years	15-30 days	PT REPORTED TO ED WITH C/O SOB/DYSPNEA, CHEST PAIN, PROBLEMS WITH INSPIRATION AND FATIGUE-TACHYCARDIA HR 119- BILATERAL LEG PAIN SINCE 4/26/21
COVID19 VACCINE	JANSEN	1273220-1	40-49 years	15-30 days	Right transverse sinus thrombus with b/l subarachnoid hemorrhage. Presented with headache and seizure. Initially treated with heparin gtt 4/27, but changed to bivalirudin gtt 4/28. The patient remains on ICU 4/30 AM on bivalirudin drip and will be transitioned to oral anticoagulants if CT of head today is stable. Patient is recovering. She will require a stay at a rehab/skilled facility at discharge for continued recovery. She remains in hospital as of today (4/30/21)
COVID19 VACCINE	JANSEN	1274234-1	50-59 years	15-30 days	Symptoms started 4/27 in patient - presented to the ED on 4/30 for sinus pain and headache. Confirmed venous sinus thrombosis on CT scan on 4/30/21 during emergency department visit. Platelets were with normal limits.
COVID19 VACCINE	JANSEN	1274347-1	30-39 years	15-30 days	On the 28th of April, 18 days from the shot, I went for a walk and came home around 6:30 p.m. to the outside of my right calf bright red and hot. I went to the ER where an ultrasound was performed and they found a DVT blood clot. I am now on an anticoagulant, Xarelto and have an appointment with my doctor on the 5th to schedule more imaging and blood work.

COVID19 VACCINE	JANSEN	1275188-1	60-64 years	15-30 days	Swelling in right leg following workout. Became painful as day went on. Swelling, pain continued. After three days, visited doctor.
COVID19 VACCINE	JANSEN	1275244-1	40-49 years	15-30 days	Experienced severe leg pain for several days. Ultrasound in ER revealed right calf DVT. Prescribed 21 day regimen of Xarelto starting yesterday.
COVID19 VACCINE	JANSEN	1275837-1	65+ years	15-30 days	Patient found to have pulmonary embolism 22 days after receiving vaccine. Onset of symptoms occurred 18-19 days after receiving vaccination, however, very likely PE related to patient hx of small cell lung cancer. He is currently hospitalized for respiratory distress as of 4/30/21
COVID19 VACCINE	JANSEN	1276463-1	60-64 years	15-30 days	lower ext DVT, started on oral anticoagulation
COVID19 VACCINE	JANSEN	1279696-1	50-59 years	15-30 days	patient reported to the pharmacy that they had to go to ER for blood clot on 04/19/2021
COVID19 VACCINE	JANSEN	1280351-1	65+ years	15-30 days	The patient developed bilateral pulmonary emboli approximately 2-3 weeks after vaccination
COVID19 VACCINE	JANSEN	1281516-1	65+ years	15-30 days	Pt experienced sever headache, loss of speech transported to Medical Center. 4/19/21 Reports overnight stay and ""blood clots"" affecting speech, causing HA. Reports clots seen around his heart on MRI Discharged 4/20/21""
COVID19 VACCINE	JANSEN	1281599-1	30-39 years	15-30 days	Culminated in myocardial infarction. Chest pains started next day and leg pains. By April 23, I had severe chest pains and had to see medical at work. On April 30, 2021 was at emergency department for heart attack symptoms. Was transferred for myocardial infarction. Test results show myocardial infarction, coronary spontaneous arterial dissection, and blood clot.
COVID19 VACCINE	JANSEN	1282273-1	60-64 years	15-30 days	Blood Clot in Right Leg
COVID19 VACCINE	JANSEN	1282451-1	65+ years	15-30 days	BLE EDMEA/PAIN, GAIT DISTURBANCE, GENERALIZED WEAKNESS PRESENTED TO ER ON 5/1/2021 SYMPTOMS STARTED ON 4/30/2021. SHE WAS FOUND TO HAVE BLE DVT. NO EVIDENCE OF CT PE. REPORTED HAD J&J COVID VACCINE ON 4/6/2021. RECENT HOSPITAL ADMIT FROM 4/28/2021 TO 4/30/2021 WITH ACUTE RENAL FAILURE AND ACUTE CYSTITIS. PT ADMITTED TO MED SURG FLOOR. CALL REC'D FROM PROVIDER NOTIFIING OF RECENT COVID VACCINE AND NEEDED VAERS REPORT COMPLETED.
COVID19 VACCINE	JANSEN	1282884-1	40-49 years	15-30 days	Large DVT and pulmonary embolism requiring anticoagulation and hospitalization. Also found to have a large fibroid uterus compressing IVC which likely contributed to IVC. Patient ended up needing mechanical thrombectomy to help relieve clot burden.
COVID19 VACCINE	JANSEN	1283019-1	40-49 years	15-30 days	Patient present to ED on 5/3 with leg pain. found to have blood clot in left leg via ultrasound. started on rivaroxaban and discharged
COVID19 VACCINE	JANSEN	1283679-1	65+ years	15-30 days	Shortness of breath leading to primary care physician clinic visit. Continued shortness of breath leading to ED visit. CT angiogram done shows bilateral pulmonary embolism. Patient is currently being treated with Eliquis.
COVID19 VACCINE	JANSEN	1284470-1	40-49 years	15-30 days	Headache onset 2 weeks after vaccination. Brain MRI on 4/30/2021 showed subacute dural venous sinus thrombosis affecting the superior sagittal, left transverse and sigmoid sinuses.
COVID19 VACCINE	JANSEN	1285193-1	65+ years	15-30 days	Multiple Blood Clots in Right Lung, clots passed through his heart and caused his death
COVID19 VACCINE	JANSEN	1285759-1	40-49 years	15-30 days	Aching left heel: April 26, progress into calf with swelling of foot, ankle & calf: evening April 27, dvt found in left leg, pulmonary emboli in both lungs, right worse than left lung, shortness of breathe, tachycardia
COVID19 VACCINE	JANSEN	1286382-1	50-59 years	15-30 days	portal vein thrombosis

COVID19 VACCINE	JANSSEN	1286545-1	65+ years	15-30 days	<p>Pt received vaccine in her home state, unable to get details of vaccine administration such as date, site, lot #, etc. Per ED MD note : 81-year-old female with reported history of atrial fibrillation found down at hotel room. Patient states she has been on the ground in the room for 3 days, she was found covered in feces. Alert and oriented x4 however intermittently appears confused and has varying history. She does not know how she got on the ground, however denies fall or syncope. No significant current complaints. Slightly tachycardic and febrile, slightly hypertensive, exam without any significant acute findings, no obvious skin source of ulcer or infection, no focal neurological deficits, no pain. Initiated aggressive fluid hydration and sepsis work-up. EKG appears normal with no signs of ischemia or arrhythmia. Labs show slightly elevated troponin, low magnesium, metabolic/lactic acidosis. VBG relatively normal. Urine negative for infection chest x-ray without evidence of pneumonia, no clinical signs or symptoms to identify source of infection. Nothing to suggest meningitis at this time. CT head is negative. Unclear source of fever however empirically treated with antibiotics and fluids. Patient remains hemodynamically stable with no hypotension. She did arrive slightly hypoxic and with increased respiratory rate however clear lung sounds and no indications of heart failure, COPD/asthma. CT chest without evidence of pulmonary embolism, focal pneumonia, or fluid overload. Respiratory status possibly related to compensation for metabolic acidosis that is likely due to lack of fluid intake due to being on the ground. CK is normal and kidney function is normal. Consulted medicine for admission for further evaluation and treatment. Cardiology was also consulted for NSTEMI, agrees with current plan. per H&amp;P 4/28/21: Altered mental status (R41.82): Etiology is not clear. Patient states she had J&amp;J Covid vaccine about 3 weeks ago. Need to rule out cerebral venous sinus thrombosis. Get a CT scan of the brain with contrast. If negative will get CT venogram or MRV and MRI of the head. Neuro checks. Request PT OT and speech therapy evaluation. Check urine drug screen. Check blood alcohol level. Non-STEMI (non-ST elevated myocardial infarction) (I21.4): Start argatroban drip until cerebral vein sinus thrombosis is excluded then we can switch to heparin drip. Start aspirin and statin. Check fasting lipid panel. Monitor on telemetry. Trend troponin. Request echocardiogram. Cardiology to consult. Dr. was consulted from the ER. + Beta-Blocker Ordered: Beta-Blocker Ordered + Aspirin Ordered: Aspirin Ordered + Statin Ordered: Statin Ordered Fall (W19.XXXA): Plan as documented above. Rhabdomyolysis (M62.82): Hydrate and recheck CPK. Elevated liver enzymes (R74.8): Check hepatitis panel. Monitor levels. Fever (R50.9): No clear source of infection. Follow up on blood cultures. CT chest negative for infectious process. Check CT of the abdomen and pelvis. Start empiric antibiotics: Vancomycin and Zosyn. Hypomagnesemia (E83.42): Administer magnesium sulfate. Repeat level in the morning. Diabetes (E11.9): Start sliding scale insulin. Monitor fingersticks. Hypoglycemic protocol. Check hemoglobin A1c. Hypertension (I10): Fortunately patient is hemodynamically stable. We will cautiously start metoprolol. Adjust antihypertensives to optimal blood pressure control. Acidosis, lactic (E87.2): Likely due to profound volume depletion. Rule out sepsis. Hydrate and trend level. VTE: Argatroban. + VTE Prophylaxis Assessment: Risk Level documented as Low Risk Discharge Planning: + Discharge Planning: + Discharge To, Anticipated: Home independently Per Intensivist note 4/30/21: .</p>
COVID19 VACCINE	JANSSEN	1287093-1	65+ years	15-30 days	<p>Right lower leg sudden onset severe swelling, pain, redness. Went to urgent care doctor who then performed assessment, blood work and ultrasound. Placed on Xarelto 15mg twice daily for 21 days.</p>
COVID19 VACCINE	JANSSEN	1288831-1	65+ years	15-30 days	<p>The pharmacy was contacted by the local health department and this is what was relayed: Patient started having leg pain and swelling on 5/1 and was concerned that it may be a blood clot. Patient then reported to the urgent care and saw. I spoke with this provider and she said that a DVT in that leg was confirmed via ultrasound and the patient was discharged with xarelto.</p>
COVID19 VACCINE	JANSSEN	1288959-1	65+ years	15-30 days	<p>Patient received vaccine on 4/10/21. Went to ED, got IV placed due to side effects. Came to clinic on 5/4/21 with right arm pain. Found to have occlusive cephalic vein clot.</p>
COVID19 VACCINE	JANSSEN	1289347-1	40-49 years	15-30 days	<p>Acute saddle pulmonary embolus with acute cor pulmonale diagnosed 4/14/2021. Treated with anticoagulation, now on Eliquis for 6 months.</p>
COVID19 VACCINE	JANSSEN	1289783-1	65+ years	15-30 days	<p>Developed COVID symptoms for a ""few"" days. Called his physician who referred him to the local hospital for suspected COVID. Tested positive for COVID at the hospital and blood clots in the lungs were discovered by CT scan. Patient was admitted to ICU for treatment. Details reported to VAERS by hospital and the Health District""</p>
COVID19 VACCINE	JANSSEN	1289959-1	60-64 years	15-30 days	<p>Developed Covid 19 infection 28 days after Johnson and Johnson vaccination. This was further complicated by bilateral pulmonary embolism requiring mechanical thrombectomy and ICU admission.</p>

COVID19 VACCINE	JANSSEN	1292635-1	60-64 years	15-30 days	She developed a DVT <4 weeks after receiving the vaccine (first became symptomatic 4/30). She has a potential alternative cause in that she was taking oral estrogen but no other provoking factor.
COVID19 VACCINE	MODERNA	0979773-1	65+ years	15-30 days	Not sure if it has to do with the COVID vaccine but her caregiver reported to me today (1/27/20201) that she passed away on 01/16/2021 from a pulmonary embolism that was 18 days after vaccine
COVID19 VACCINE	MODERNA	0995017-1	40-49 years	15-30 days	On 1/28/2021 at 0545 hours as I was on my way into work when I started to have severe right side chest pain, so much so that I had to pull over. Shortly thereafter ambulance arrived on scene at which time it was determined that I would be transported to the hospital. Once there, a series of tests were conducted, one of which was a D-Dimer blood test to rule out blood clots. That resulted in an elevated count to which a CT scan was ordered. The result of the CT scan revealed that I had 2 Pulmonary Embolisms, one in the upper lobe of my right lung and one in the middle lobe of my right lung. Due to me being what the doctors said was a healthy 45 year old with no underlying conditions or signs of DVT (deep vein thrombosis) they deemed me low risk at that time and advised I was at low risk of dying in the next 30days. However, they advised that at any time, the clot could possibly become dislodged and cause worse problems, possibly death if time is not given to the body to dissolve the clots. Ultimately it was determined that I be discharged and prescribed blood thinning medications to help thin the blood to prevent further clotting should I have a clotting issue (undetermined at this time).
COVID19 VACCINE	MODERNA	0995346-1	60-64 years	15-30 days	Tightness in chest several times about 1 week and 2 weeks after 1st round. Difficulty sleeping on left side 20 and 21 days following 1st round. Severe pain with inhaling AM of 22 day. Diagnosed at ER Hospital, with DVT left calf and PE both lungs. On Heparin IV for 4 days inpatient. Now on Eloquis 10mg BID for a week, 5mg BID thereafter.
COVID19 VACCINE	MODERNA	1015638-1	60-64 years	15-30 days	Deep vein thrombosis; pulmonary embolism; A spontaneous report was received from a 64-year-old female consumer who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed deep vein thrombosis and pulmonary emboli. The patient's medical history was not provided. Concomitant product use was not provided. On 05 Jan 2021, approximately 3 weeks prior to the onset of the events, the patient received first dose of mRNA-1273 (Lot number: 037K20A) intramuscularly for prophylaxis of COVID-19 infection. On 26 Jan 2021, the patient reported she was hospitalized for deep vein thrombosis and pulmonary emboli. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, deep vein thrombosis and pulmonary emboli, were considered unknown.; Reporter's Comments: This case concerns a 64-year-old, female patient. The patient's medical history was not provided. The patient experienced serious, unexpected event of Deep vein thrombosis and pulmonary embolism. The events occurred 22 days after the first dose of mRNA-1273 (Lot number: 037K20A) administration. Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Additional information has been requested for further assessment.
COVID19 VACCINE	MODERNA	1026132-1	30-39 years	15-30 days	Bilateral unprovoked pulmonary embolisms. Started anticoagulation therapy

COVID19 VACCINE	MODERNA	1038305-1	50-59 years	15-30 days	<p>On January 21, 2021 I started feeling pains in my right shoulder (1st shot was left shoulder) and the following day it had spread across my body, shoulders, chest, arms, legs and calves. I also had a severe headache along with the muscle pains and woke up each day since in a pool of sweat with the sheet soaked to this day. Due to the severe muscle pains, I started taking Tylenol and all the symptoms pointed to the virus itself. I was tested for the virus on Monday, January 25th with negative results on the morning of the 26th. I continued to self-medicate with Advil every four hours to remove the severe muscle pains noted above. To back track slightly, I had a colonoscopy on January 19, 2021 and one large polyp was removed without issue. Due to the full body muscles pains and taking the Advil, it likely caused bleeding from the polyp site of the colonoscopy and went to the ER and they transferred me back the hospital on January 28, 2021, the location of the colonoscopy, and hospital found nothing wrong with the colonoscopy during my 2.5 day stay there. The did an x-ray of my chest to test for the flu and related items and found everything to be clear. They also a CT of my abdomen to look for any abnormalities and found none. Through all this the muscle pains continued when I would move, the muscles would fire up and intense pain persisted until I could calm them down after about 30 mins of intense pain. Hospital also tested me twice for the COVID virus and each turned out negative. Overall, I've been tested for the virus nearly 12 times and all were NEGATIVE. From the visit to Hospital, with the colonoscopy and no additional bleeding occurring, Hospital gave me a steroid called Prednisone to mask the pain on Saturday, January 30, 2021 at about 1pm and by 4pm they fully released me with no idea what was causing the severe muscle pain across my body when I moved. I literally just walked out of the hospital since the steroid masked the muscle pain issue. The steroids worked but I was still walking up in a pool of sweat and very clammy and wet each morning from 1am until I woke up. On February 2, 2021 I had 3 bowel movements that were all dark purple and full of blood clots which led me back to Hospital and the ER could not get in touch with the Hospital Doctors for transfer so they admitted me to the Hospital, thank God. On February 4, 2021 Methodist performed an emergency colonoscopy to clamp the polyp site, took two additional polyps out and did an endoscopy to ensure my upper and lower GI track were clear, and it was and the two additional polyps were benign. Through all this the serve muscle pains persisted and Hospital moved me to a patient room and out of the ER. Over the next several days, February 4 thru the 11th Hospital cleared me of everything they could test for, over 85 different tests were ran based on MyChart. All my blood counts were all over the place, WBC were 19,000, Platelets were nearly 700, my sedimentation rate reached 64+ and the server muscle pains persisted and I was basically incapacitated during my entire stay at Hospital. Hospital had several specialists seem me from Internal Medicine, Infectious Disease, Neurology to Rheumatoid ologist and none of them found anything wrong with me other than my COVID anti-bodies were enormously high with not signs of slowing down. The conclusion by each of the specialist is that my symptoms all point to an Adverse Level 3 Inflammatory Reaction to the first COVID Vaccine shot. The Infectious Disease specialists emphasized that I DO NOT get the second vaccine shot since it would like have killed me. (We had cancelled my 2nd shot, scheduled for February 3, 2021 via Cancer</p>
COVID19 VACCINE	MODERNA	1041500-1	65+ years	15-30 days	<p>Patient presented to the ED 2/15/2021 for shortness of breath and lightheadedness with near syncopal event. The pt reported 2 episodes of SOB and lightheadedness, with the second one as the more severe. On her second episode, she felt severe shortness of breath, tried to walk quickly to her bed with her walker, and fell into her bed. CT angio demonstrated acute saddle PE, mild right heart strain, RUL pulmonary infarct, and mild multifocal pneumonia with suspicion of COVID; IR was consulted and suggested thrombectomy due to the severity of the embolism. In the ED, she was started on heparin drip and put on low-flow NC oxygen without distress. Upon arrival to the emergency department her vital signs were significant for T 36.4, SBP 120/81, HR 95 bpm, NSR, RR 18, FiO2 94% on room air. Her oxygen increased to 98% on 2 L nasal cannula. Her laboratory values revealed WBCs 15.1, Hb 14.4, HCT 43.4, PLT 321, neutrophils 68.8%, D-dimer 4642, NA 134, K3.4, anion gap 9, BUN 17, creatinine 1.00, glucose 163, troponin elevated 0.12, 0.25, and 0.41, urinalysis is unremarkable, COVID-19 swab is positive. A thrombectomy was performed 2/16/2021. She tested COVID positive on 2/16/2021 and her SpO2 remains in the high 90s with dips to mid 80s while talking, but she does not currently experience any SOB.</p>
COVID19 VACCINE	MODERNA	1042458-1	65+ years	15-30 days	<p>Patient admitted with acute stroke, no prior history of same. Mild hyperlipidemia, but otherwise no clear risk factors for stroke. Unclear if anything to do with COVID vaccine.</p>
COVID19 VACCINE	MODERNA	1052095-1	30-39 years	15-30 days	<p>DVT left lower extremity</p>

COVID19 VACCINE	MODERNA	1057548-1	50-59 years	15-30 days	bilateral pulmonary embolism; multiple areas of infarct; back pain; atelctheisis; chest pain; left leg pain; deep vein thrombosis; pulmonary effusions; fever; Chills; myalgia; A spontaneous report was received from a physician who was also a 55-year-old, previously healthy male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced fever/pyrexia, chills, myalgia, chest and back pains, bilateral pulmonary embolism/pulmonary embolism, multiple areas of infarct/pulmonary infarct, atelctheisis/atelectasis, left leg pain, and deep vein thrombosis. The patient's medical history included daily exercise and no personal or family history of clotting issues and no trauma. Products known to have been used by the patient were not provided. On 02 Jan 2021, prior to the onset of the events, the patient received the first of two planned doses of mRNA-1273 (Lot number: 039k20-2a) intramuscularly for prophylaxis of COVID-19 infection. On 30 Jan 2021, approximately 28 days after the first dose, and prior to the onset of symptoms, the patient received the second of two planned doses of mRNA-1273 (Lot number: 012m20a) intramuscularly for the prophylaxis of COVID-19 infection. On 30 Jan 2021, the patient reports that for the first 18 hours, he experienced fever, chills and myalgia. On 01 Feb 2021, the patient reports that he thought the myalgia was continuing, as he had pain in his chest and back. The chest pains gradually worsened. On 05 Feb 2021, the patient went to the emergency room and was admitted. He was diagnosed with a pulmonary embolism. He was started on enoxaparin sodium but switched to apixaban. A computerized tomography study of the lungs showed that he had bilateral pulmonary embolism, multiple areas of infarct and atelectasis. His dimer was 4800. COVID-19 test was negative. An echocardiograph was performed, no results were reported. An ultrasound of the legs was performed and ruled out deep vein thrombosis. Date of discharge was not specified. On an unknown date two days after discharge, the patient experienced left leg pain and returned to the emergency department. Patient was diagnosed with deep vein thrombosis that ran the entire length of the femoral artery. Patient was switched back to enoxaparin sodium and taken off the apixaban. A repeat computerized tomography study was done to see if the pulmonary embolism was progressing and it was not, however, it showed pulmonary effusions. All current lab work was reported as normal, except for an increased prothrombin time. COVID-19 test was negative. Patient continues to be followed by a pulmonologist and hematologist. Consent to contact patient, pulmonologist and hematologist was obtained. Action taken with mRNA-1273 was not applicable. The outcome of the events, fever/pyrexia, chills, myalgia, chest and back pains, bilateral pulmonary embolism/pulmonary embolism, multiple areas of infarct/pulmonary infarct, atelctheisis/atelectasis, left leg pain, and deep vein thrombosis, was considered not resolved.; Reporter's Comments: Very limited information regarding this events has been provided at this time. Further information has been requested. Company assessed the events to be unlikely related to company product.
COVID19 VACCINE	MODERNA	1059327-1	65+ years	15-30 days	Moderna COVID-19 Vaccine EUA. PT - Multiple blood clots both lungs (no other presentable causes i.e. diagnosed as unprovoked).
COVID19 VACCINE	MODERNA	1067194-1	40-49 years	15-30 days	developed fever and chills within 24 hours of vaccine and at 4 weeks out had unprovoked acute DVT in the axillary and subclavian vein on the side of the vaccine.
COVID19 VACCINE	MODERNA	1082086-1	65+ years	15-30 days	Patient was vaccinated at pharmacy on 2/9/2021, first dose of Moderna COVID-19 vaccine. Per medical records from hospital: patient developed fever, diarrhea, nausea and abdominal pain on 2/25/2021 and presented to the hospital E.R. on 3/1/2021. Patient was diagnosed with Sepsis and Pneumonia. Cardiac arrest on 3/6/21, renal failure, seizures. Patient tested negative for COVID-19 on 3/1/2021 and 3/8/2021. Patient has declined, was placed intubated and placed on a ventilator. Patient admitted to hospice services on 3/8/2021 and plan is for compassionate removal of life support at hospice. Prognosis is poor.

COVID19 VACCINE	MODERNA	1083722-1	65+ years	15-30 days	Pulmonary embolism; tested positive for covid; A spontaneous report was received from a consumer concerning an 84-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced pulmonary embolism, and tested for positive for Covid-19/COVID-19. The patient's medical history included arthritis, and high blood pressure. Concomitant medication history was not provided. On 26-Jan-2021, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) intramuscularly for prophylaxis of COVID-19 infection. On 12-Feb-21, she started experiencing shortness of breath and went to her local urgent care. They sent her to the emergency room where she was admitted and diagnosed with a Pulmonary Embolism. The patient was prescribed a blood thinner. While in the hospital, she tested positive for Covid-19 on 14-Feb-21. She was in the hospital from 12-Feb-21 to 22-Feb-21. Action taken with mRNA-1273 in response to the events was not reported. The outcome of events, pulmonary embolism were recovered. The outcome of the event, COVID-19 was recovering.; Reporter's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested. Based on the current available information and the mechanism of action of mRNA-1237 vaccine, the event of Covid-19 is assessed to be unlikely related.
COVID19 VACCINE	MODERNA	1086928-1	50-59 years	15-30 days	Chose not to get second shot; Deep Vein Thrombosis; A spontaneous report was received from a consumer, concerning a 50 year-old, female who received Moderna (mRNA-1273) and developed deep vein thrombosis, and chose not to get second shot. The patient's medical history was not provided. Concomitant product was not provided. On 07Jan2021 (previously reported as 16Jan2021), approximately one week prior to the onset of symptoms, the patient received their first of two planned doses of mRNA-1273 (batch number: 025L20A) intramuscularly for prophylaxis of COVID-19 infection. A week post vaccination, she had a thick painful cord down injection arm and was misdiagnosed with tendonitis. After a second opinion, she was diagnosed with deep vein thrombosis. On 01FEB2021, an ultrasound confirmed a blood clot and subsequently, she went to the ER. A computerized tomography (CT) of the lungs ruled out pulmonary embolism. Based on these events, the patient chose not to get the second shot. Treatment included rivaroxaban and follow-up with hematologist. The second dose of mRNA-1273 was discontinued in response to the event. The outcome of the events deep vein thrombosis and chose not to get second shot were unknown. Follow-up information received 08Feb2021 included additional event, date of first dose was updated from 16Jan2021 to 07Jan2021, diagnostic test and treatment.; Reporter's Comments: This case concerns a 50 year-old, female who experienced deep vein thrombosis. Treatment included rivaroxaban and follow-up with hematologist.Very limited information regarding this event has been provided at this time. Further information has been requested. The causality for the event of intentional dose omission is assessed to be not applicable.
COVID19 VACCINE	MODERNA	1092401-1	50-59 years	15-30 days	I was swimming in a lake when suddenly I couldn't breath and my heart started pounding. I was gasping for air. My pulse went from a normal working out pulse to above 145 bps. It did not come down when floating on my back or resting when I eventually got back into shore. Then when I got home I had to climb stairs and I lost my breath again.
COVID19 VACCINE	MODERNA	1092904-1	65+ years	15-30 days	Developed tachycardia and shortness of breath on 3/1/21 which was significantly worse on 3/2/2021. Went to ER and CT angio showed diffuse bilateral pulmonary embolism. Spent the night for heparin, telemetry monitoring and lab work.
COVID19 VACCINE	MODERNA	1093973-1	65+ years	15-30 days	Superficial thrombophlebitis of the right Superficial Saphenous Vein in otherwise healthy and active patient
COVID19 VACCINE	MODERNA	1095030-1	50-59 years	15-30 days	After 1st injection (1/11/21) experienced severe shortness of breath with minimal activity with accelerated heart rate and drop in O2 stat. within 2 days of injection then developed wheezing cough. Primary MD prescribed Augmentin nd prednisone with eventual success. With normal blood work, chest x-ray and negative Covid test all done by 1/15. On 3/9/21 (28) days after second dose (2/11/21) experienced burning and swelling on right leg. Went to Hospital, ER and found extensive blood clots in right leg and saddle pulmonary embolism . Also had 50% Platelet blood count decrease since the 1/15 bloodwork Admitted for 3 nights on heparin dip. Discharge on home Lovenox injections for 30days.
COVID19 VACCINE	MODERNA	1100924-1	60-64 years	15-30 days	DVT blood clot in left calf verified via ultrasound on 2/17/2021. Symptoms: pain in left calf and foot proceeded by chills/fever and right fingers/hand inflammation. Symptoms began 2/08/2021.

COVID19 VACCINE	MODERNA	1101152-1	65+ years	15-30 days	Blood clot on right lung; soreness in arm; A spontaneous report was received from a 72 year old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced blood clot on right lung (pulmonary embolism) and myalgia. The patient's medical history was not provided. The patient had family history of blood clot (mother and brother). No concomitant product use was reported. On 02-Feb-2021, the patient received her first of two planned doses of mRNA-1273 (Lot number: 011M20A) intramuscularly for prophylaxis of COVID-19 infection. The patient had soreness in the right arm which subsided couple of days later. The patient also experienced shortness of breath for a week after vaccine administration. On 17-Feb-2021, the patient went to the hospital and underwent COVID-19 virus test, the results of which were negative. On 17-Feb-2021, the computerized tomography scan on chest showed moderate size blood clot on right lung. On 18-Feb-2021, the patient was discharged from the hospital on recommendation to initiate and continue lifetime treatment with Eliquis (apixaban, 5mg every 12 hours). According to the physician, moderate size blood clot on right lung of the patient could be attributed to the genetic history (patient's mother and brother also had blood clot). The patient also followed up with primary care physician, who informed that it was genetic and not related to vaccine. Action taken with mRNA-1273 was not reported. The outcome of the events, pulmonary embolism was unknown. The outcome of the event, myalgia was considered as recovered/resolved.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1103001-1	50-59 years	15-30 days	Development of blood clots in lower right leg causing swelling and pain. Pt. visited doctor who prescribed an ultrasound which revealed the clots. Doctor has now put pt. on blood thinners indefinitely.
COVID19 VACCINE	MODERNA	1104706-1	30-39 years	15-30 days	Unprovoked Pulmonary Embolism - symptom onset week of 1/18, hospitalized 1/30-1/31 - treated with oral anticoagulants
COVID19 VACCINE	MODERNA	1105092-1	65+ years	15-30 days	PT WAS VACCINATED WITH SECOND MODERNA DOSE ON 02/16/2021 . DR CALLED ME TO INFORM OF PT ADVERSE EVENT. PT PRESENTED TO DR WITH SWELLING IN LEFT LOWER LEG. DR ORDERED VENUS DOPLAR SHOWING A LARGE BLOOD CLOT FROM PT'S GROIN TO HER CALF MUSCLE. DUE TO NO PREVIOUS HX OF CLOTTING OR BLOOD DISORDERS NOR FAMILY HX AND PROXIMITY TO VACCINATION, DR BELIEVES VACCINE CAUSED THE CLOT. DR PLACED PATIENT ON ELIQUIS. DR WISHES TO BE CONTACTED IF FURTHER DETAIL IS NEEDED.
COVID19 VACCINE	MODERNA	1106428-1	65+ years	15-30 days	Sub-Clavian Vein Blood Clot
COVID19 VACCINE	MODERNA	1106509-1	65+ years	15-30 days	Pain/swelling in left arm. Sent for venous duplex doppler. Results show: DVT in LUE
COVID19 VACCINE	MODERNA	1107219-1	30-39 years	15-30 days	Bilateral unprovoked pulmonary embolisms; A spontaneous report was received from a consumer concerning a 35-years-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced bilateral unprovoked pulmonary embolisms. The patient's medical history was not reported. Concomitant product use was not reported. On 14-Jan-2021, prior to the onset of the event, the patient received their first of two planned doses of mRNA-1273 (Lot number: not provided) intramuscularly for prophylaxis of COVID-19 infection. On 31-Jan-2021, approximately 17 days after receiving vaccine, the patient was diagnosed with bilateral unprovoked pulmonary embolisms after a chest computerized tomogram (CT) was performed. Treatment included hospitalization and starting of anticoagulation therapy. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the event was considered not resolved. The reporter did not provide the causality assessment for the events.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.
COVID19 VACCINE	MODERNA	1107735-1	65+ years	15-30 days	Death on March 8 due to a large blood clot at the base of his brain. This was 16 days after inoculation.
COVID19 VACCINE	MODERNA	1108629-1	65+ years	15-30 days	Patient developed shortness of breath upon exertion on 2/16/21 after receiving his second COVID vaccine on 2/12/21. He had an office visit on 3/3/21 with his PCP where he was found to have an elevated d-dimer. He was sent to the ED for a CT-scan that confirmed an acute bilateral pulmonary embolism with large burden of thrombus within the right lung. He was admitted from 3/3 to 3/11. He underwent a pulmonary arterial embolism on 3/5. He was also on a heparin drip while inpatient. He was discharged on Eliquis.
COVID19 VACCINE	MODERNA	1115126-1	65+ years	15-30 days	His breathing problem worsened on 02/23/2021, short of breath and tired. He died of a pulmonary embolism and heart attack in the hospital on 3/9/21 after being there for 9 days.

COVID19 VACCINE	MODERNA	1115408-1	50-59 years	15-30 days	submassive pulmonary embolism R&L lungs
COVID19 VACCINE	MODERNA	1117769-1	65+ years	15-30 days	Just under 3 weeks after last dose, development of left popliteal/distal femoral vein deep venous thrombosis with several small bilateral pulmonary emboli. Symptoms were about 4 days of increasing discomfort left calf, edema, pain in region of left gastrocnemius muscle, depend erythema, all not responsive to NSAIDS. I was hospitalized overnight for assessment and treatment. Started on heparin, switched to Eliquis. So far, no complications.
COVID19 VACCINE	MODERNA	1124727-1	65+ years	15-30 days	Pulmonary Embolism Multiple blood clots in legs and lungs
COVID19 VACCINE	MODERNA	1125686-1	65+ years	15-30 days	Patient experienced severe nausea and dizziness in the evening on 3/9/21 and lost consciousness in her kitchen. She was taken to the ER the next morning and was diagnosed with a pulmonary embolism and acute DVT in the right popliteal vein and right calf veins. Patient was treated with EKOS and discharged on 3/13/21 on Apixiban.
COVID19 VACCINE	MODERNA	1128208-1	65+ years	15-30 days	bilateral pulmonary emboli
COVID19 VACCINE	MODERNA	1134860-1	65+ years	15-30 days	bilateral pulmonary emboli
COVID19 VACCINE	MODERNA	1137221-1	65+ years	15-30 days	Blood clots in both legs; Cramps and spasms on her right and left legs; Painful nodules under both arms and shoulders; Itching down to her toes and left side of the body; Injection site itching; A spontaneous report was received from a consumer concerning a 79-year-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced Cramps and spasms on her right and left legs, injection site itching, itching down to her toes and left side of the body/pruritus, painful nodules under both arms and shoulders/nodules and blood clot in both legs/Thrombosis. Medical history was not reported. Concomitant medications included losartan, cetirizine hydrochloride and pantoprazole. On 30 Jan 2021, the patient received her first planned dose of mRNA-1273 (batch number: 007MZ0A) intramuscularly for prophylaxis of COVID-19 infection. On 27 Feb 2021, she had her second planned dose of mRNA-1273 (batch number: 01021A) intramuscularly on left arm. Soon, she developed itching at injection site down to her toes and left side of the body. She developed painful nodules on shoulders as well as both under arms and it was mentioned that the one on left side was severe. On 09 Mar 2021, she began experiencing cramps and spasms on her right and left legs. She was diagnosed with blood clots in both legs while in the emergency room (ER). She was treated with hydroxyzine and apixaban. The event blood clot in both legs was considered to be medically significant. The action taken with mRNA-1273 in response to the events injection site itching, itching down to her toes and left side of the body, painful nodules under both arms and shoulders and blood clot in both legs was unknown. The outcome of the events Cramps and spasms on her right and left legs, injection site itching, itching down to her toes and left side of the body and blood clot in both legs was unknown whereas painful nodules under both arms were still sore but better.. The reporter did not provide any causal relationship between mRNA-1273 and the events injection site itching, itching down to her toes and left side of the body, painful nodules under both arms and shoulders and blood clot in both legs.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1138841-1	40-49 years	15-30 days	Common iliac vein thrombosis
COVID19 VACCINE	MODERNA	1140107-1	50-59 years	15-30 days	had a Pulmonary Embolism

COVID19 VACCINE	MODERNA	1142915-1	50-59 years	15-30 days	Blue/black blood clot on middle finger right hand; Burning in middle finger on right hand; Itchiness on middle finger on right hand; Pain in middle finger on right hand; A spontaneous report was received from a Consumer concerning a 55-years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events burning in middle finger on right hand/burning sensation, itchiness on middle finger on right hand/pruritus, pain in middle finger on right hand/pain in extremity, blue black blood clot on middle finger right hand/thrombosis. The patient's medical history was not provided. No relevant concomitant medications were reported. On 2 Jan 2021, prior to the onset of the events the patient received their first of two planned doses of mRNA-1273 (lot batch: 037K20A) intramuscularly for prophylaxis of COVID-19 infection. On 20 JAN 2021 1.00 pm, after taking mRNA-1273, the patient felt weird sensation in right hand middle finger. She felt burning, itchiness, pain and had a dark blue/black blood clot on inside of finger. 2 hours later it started to fade down (purple in color). In the evening it was considerably lighter. On 21 Jan 2021 there was a light imprint of the blood clot. Blood clot went away later that day. Patient did not received treatment. Action taken with mRNA-1273 in response to the events was not reported. On 20 Jan 2021 the outcome of events burning in middle finger, itchiness on middle finger on right hand, pain in middle finger on right hand was resolving. On 21 Jan 2021 the outcome of event blue black blood clot on middle finger right hand was resolved.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested.
COVID19 VACCINE	MODERNA	1143261-1	60-64 years	15-30 days	Large volume obstructive PEs with bilateral pleural and pericardial effusions
COVID19 VACCINE	MODERNA	1144392-1	65+ years	15-30 days	Last Moderna vaccine March 3, 2021. On March 17 began not feeling well. Never felt this way. Then on March 25 had severe low abdominal pain that sent her to ER.
COVID19 VACCINE	MODERNA	1144434-1	65+ years	15-30 days	Pt received Covid-19 Moderna vaccine dose #1 on 1/23/21. Dose #2 administered on 2/20/21 @ 12:43pm. Pt presented to on 3/9/21 w/ complaints of localized edema x1-2 days in the left lower leg. (Symptoms started 3/7/21). Pt denied associated calf or extremity pain but reported she went shopping on Saturday and walked ""alot."" Pt reported she could walk on it but it ""felt funny & tight"" so she took an extra furosemide 40mg on 3/8/21. Trace edema in right ankle, 3+ pitting edema left leg from knee distally, slight increased warmth, no calf tenderness, negative Homan's sign, extremity asymmetric. Pt referred for venous doppler (unilateral, left leg, left leg edema, . Findings: acute, occlusive DVT in one of the duplicated left FV, the left popliteal vein, peroneal vein, & PTV. Superficial phlebitis and phlebothrombosis left GSV. per, FASC, RVPI 3/9/21 @ 2:27pm. Pt sent to ED for evaluation. Pt started on Xarelto in ED, changed to Eliquis per Dr. Eliquis 5mg PO BIDx7 days, then 5mg PO BID.""
COVID19 VACCINE	MODERNA	1148421-1	65+ years	15-30 days	At 2AM on Saturday, March 13, 2021, I began passing blood into the toilet. That evening I went to the Emergency Department and was admitted as an inpatient. I was treated there and discharged to home on Tuesday, March 16. Over the next two days I passed substantial amounts of coagulated blood. My diagnosis was colitis.

COVID19 VACCINE	MODERNA	1148711-1	65+ years	15-30 days	Her leg started bothering her, the pain was quite heavy and consistent; pain under her left arm; blood cloth in her leg; a little nauseous; headache; tired; pins; A spontaneous report was received from a consumer concerning a female patient of 70-years-old, who received Moderna's COVID-19 vaccine(mRNA-1273) and experienced Pins/ Paraesthesia,nausea,tiredness,headache,pain in leg was quite heavy and consistent, blood cloth in leg, pain under left arm. The patients medical history was not provided .Concomitant medications reported included Eliquis starter pack twice a day,Latanoprost for Glaucoma,Omeprazole for heart burn. On 15 Jan 2021,prior to the onset of events, the Patient received their first of two planned dose of mRNA-1273(Lot number: 037K20A) vaccine via unknown route for prophylaxis of COVID-19 infection. On 12 Feb 2021,prior to the onset of events, the Patient received their second of two planned dose of mRNA-1273(Lot number: 024M20A) vaccine via unknown route for prophylaxis of COVID-19 infection On 12 feb 2021,That evening she got pins again.The next day she was a little nauseous, tired and had a headache. Her leg started bothering her 3 days to a week after the second dose.And the pain in her leg was quite heavy and consistent, she thought it might be her sciatica. She went to the doctor and ended up getting a doppler and they discovered a blood clott there. She had never had a blood clott before in her life.she was feeling pain under her left arm as well. No Treatment for the event was provided. Action taken with the mRNA-1273 in response to the event was not applicable. the event pins were considered resolved on 13 Feb 2021. The events nauseous,tiredness,headache were considered resolved on 14 Feb 2021. The outcome of the events pain in leg was quite heavy and consistent, blood cloth in leg, pain under left arm was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of these events, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1148935-1	65+ years	15-30 days	developed extensive DVT of LLE and PE on approx 3/27 admitted to hospital on 3/29
COVID19 VACCINE	MODERNA	1153993-1	65+ years	15-30 days	Pulmonary embolism; A spontaneous report was received from a consumer who is a 74-year old, female who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed a pulmonary embolism. The patient's medical history included hypertension, obesity, chronic obstructive pulmonary disease, lung cancer, bladder cancer, and meningioma. Products known to have been used by the patient, within two weeks prior to the event, included olmesartan, vitamin D3, calcium carbonate, and nebivolol hydrochloride. On 08-JAN-2021, prior to the onset of the events, the patient received the first of two planned doses of mRNA-1273 (Batch number: 031L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 04-FEB-2021, the patient was diagnosed with a pulmonary embolism. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events, pulmonary embolism is unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1159153-1	65+ years	15-30 days	29 days after patient's second Moderna dose, she had sudden onset significant pain where she couldn't stand or walk, her left leg became swollen twice it's size, and blue. She went to the ER with no treatment. About 5-6 hours after discharged she returned with her leg turning purple and uncontrollable pain. She was diagnosed with venous thromboembolism and transferred to a larger facility where she underwent lytic therapy and venous angioplasty. She is having to go for venous stenting in the next two weeks. She continues to have pain in her leg, chronic fatigue and weakness, as well as being lightheaded with a stable BP (no orthostasis). She has been diagnosed with anemia since vaccination and is being worked up for that.
COVID19 VACCINE	MODERNA	1172529-1	65+ years	15-30 days	Blood clot that caused total vision loss in right eye. It occurred on 04/03/2021. Was treated by ophthalmologist at eye Center, and at Hospital,
COVID19 VACCINE	MODERNA	1172623-1	65+ years	15-30 days	Pain in abd and side started on Saturday, patient reported to hospital on 4/6 found on CT scan to have: Multifocal patchy occlusive and nonocclusive PE involving the bilateral lower lobe and right upper lobe segmental and subsegmental pulmonary arteries. Suggestion of flattening of the interventricular septum raising the possibility of right heart strain. Peripheral airspace opacities in the bilateral lower lobes, left more than right, which could relate to a combination of evolving pulmonary infarcts and/or hypoventilatory changes. Small left pleural effusion.

COVID19 VACCINE	MODERNA	1173594-1	65+ years	15-30 days	Blood clot on his left leg, from his groin to his ankle/still having the blood clot; A spontaneous report was received from a consumer concerning an 80-years-old male patient, who received Moderna's COVID-19 vaccine (mRNA -1273) and had blood clot on his left leg, from his groin to his ankle. The patient's medical history was not provided. No relevant concomitant medications were reported. On 02 Jan 2021, prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number: 039KZ014) intramuscularly for prophylaxis of COVID-19 infection. On 30 Jan 2021, approximately two weeks prior to the onset of the symptoms, the patient received their second of two planned doses of mRNA-1273 (Batch number: unknown) via unknown route in the left arm for prophylaxis of COVID-19 infection. On an unknown date in Feb 2021, the patient reported having a medically significant event, blood clot on his left leg, from his groin to his ankle and is still having it. The patient taking medication for it. The patient received both scheduled doses of mRNA-1273 prior to the events, therefore action taken with the drug in response to the events was not applicable. At the time of this report, the outcome of the event had blood clot on his left leg, from his groin to his ankle was not resolved.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1178260-1	30-39 years	15-30 days	This spontaneous case was reported by a nurse (subsequently medically confirmed) and describes the occurrence of DEEP VEIN THROMBOSIS (Venous thrombosis in her left leg/clot was in left leg) in a 37-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 011M20A and 011J20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included LEVOTHYROXINE SODIUM (SYNTHROID) and TOPIRAMATE (TOPAMAX) for an unknown indication. On 04-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 02-Feb-2021, the patient experienced TACHYCARDIA (Severe Tachycardia/ Still very tachycardia) and FEELING ABNORMAL (Felt a little weird). On 03-Feb-2021, the patient experienced DYSPNOEA (Difficulty breathing), FATIGUE (Could not get up), ASTHMA (Asthma) and ASTHENIA (Could not get up). On 04-Feb-2021, the patient experienced CONTUSION (Bruise on her right and left leg) and VACCINATION COMPLICATION (Had a reaction to the vaccine). On 01-Mar-2021, the patient experienced DEEP VEIN THROMBOSIS (Venous thrombosis in her left leg/clot was in left leg) (seriousness criterion medically significant). On an unknown date, the patient experienced HAEMOGLOBIN DECREASED (Hemoglobin decreased) and RED BLOOD CELL COUNT DECREASED (Red blood cells are low). At the time of the report, DEEP VEIN THROMBOSIS (Venous thrombosis in her left leg/clot was in left leg), TACHYCARDIA (Severe Tachycardia/ Still very tachycardia), DYSPNOEA (Difficulty breathing), FEELING ABNORMAL (Felt a little weird), FATIGUE (Could not get up), ASTHMA (Asthma), CONTUSION (Bruise on her right and left leg), ASTHENIA (Could not get up), VACCINATION COMPLICATION (Had a reaction to the vaccine), HAEMOGLOBIN DECREASED (Hemoglobin decreased) and RED BLOOD CELL COUNT DECREASED (Red blood cells are low) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In March 2021, Haemoglobin: low gram per litre (Low) LOW. In March 2021, Red blood cell count: low cells per microlitre (Low) LOW. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment informations reported were Levalbuterol tartrate and Rivaroxaba 20 mg This case was linked to MOD-2021-059897 (Patient Link).
COVID19 VACCINE	MODERNA	1179485-1	30-39 years	15-30 days	Pulmonary Embolism
COVID19 VACCINE	MODERNA	1182180-1	65+ years	15-30 days	Diagnosed on 2/4/21 with a dvt blood clot in my left leg. Currently on warfarin.
COVID19 VACCINE	MODERNA	1182665-1	40-49 years	15-30 days	He had second dose of Moderna COVID vaccine on March 13th. He was admitted with progressive SOB and acute right leg limb ischemia 4/7/21. He was found to have massive Bilateral PE and right common femoral artery and right external iliac atery occlusion. He was unstable and required embolectomy, tPA and EKOS for PE and embolectomy for right leg arterial occlusions. He remains sedated in ICU now.
COVID19 VACCINE	MODERNA	1183234-1	65+ years	15-30 days	On 3/4/2021 I was diagnosed with metastatic lung cancer which further studies showed that there were innumerable bone and organ metastases. On 3/12/2021 I was further diagnosed with multiple pulmonary emboli.

COVID19 VACCINE	MODERNA	1183418-1	65+ years	15-30 days	Vaccine breakthrough hospitalization - SOB with O2 sat 50% when EMS arrived. On non-rebreather sitting 70%. Chills, fever, cough, and chest pain. BP 152/79, HR 93, RR 20, SpO2 91%. Had been scheduled to receive COVID mAb day of admission, but clinical course worsened. Admitted to Medical ICU for acute respiratory failure with hypoxia and ARDS secondary to COVID-19. Placed on BIPAP and Rx with Remdesivir, dexamethasone, & tocilizumab. Treated for presumed pulmonary embolism with full-dose anticoagulation. Pt expressed wishes to remain DNR/DNI, ultimately she elected to transition to comfort measures only given worsening hypoxia.
COVID19 VACCINE	MODERNA	1188275-1	65+ years	15-30 days	Pulmonary Embolism with Acute Core Pulmonale -no sign of DVT. Multiple blood clots in major arteries of both lungs. Event began with tiredness over about. 2 week period and ended in acute event with trouble breathing. Taken to hospital via ambulance. Tests also showed right heart damage due to stress from clots.
COVID19 VACCINE	MODERNA	1193450-1	65+ years	15-30 days	Extensive arterial thrombus of the left lower extremity. Partial right lower extremity thrombus. Interventions include heparin therapy and evaluation by cardiovascular surgery and interventional radiology
COVID19 VACCINE	MODERNA	1194117-1	65+ years	15-30 days	Blood clot in lung; fever; Difficult breathing; This spontaneous case was reported by a consumer and describes the occurrence of PULMONARY EMBOLISM (Blood clot in lung) and DYSPNOEA (Difficult breathing) in an 84-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 010A21A and 007M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). Concurrent medical conditions included Hypertension. On 28-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 20-Feb-2021, the patient experienced DYSPNOEA (Difficult breathing) (seriousness criterion medically significant). On 27-Feb-2021, the patient experienced PULMONARY EMBOLISM (Blood clot in lung) (seriousness criteria hospitalization and medically significant) and PYREXIA (fever). At the time of the report, PULMONARY EMBOLISM (Blood clot in lung), DYSPNOEA (Difficult breathing) and PYREXIA (fever) outcome was unknown. Treatment details included Heparin, Xarelto. Based on the current available information a temporal association between the use of the product and the onset date of the events, and with reoccurrence of blood clot with second vaccine use, causal relationship with the events cannot be excluded. Fever is consistent with the known safety profile of the vaccine.; Sender's Comments: Based on the current available information a temporal association between the use of the product and the onset date of the events, and with reoccurrence of blood clot with second vaccine use, causal relationship with the events cannot be excluded. Fever is consistent with the known safety profile of the vaccine
COVID19 VACCINE	MODERNA	1194755-1	50-59 years	15-30 days	Arm soreness for a couple days Diagnosed with Extensive DVT 2/27/2021 and PE in Left lower lung; May Thurner Syndrome Thrombectomy & stent with IVC filter 3/11/2021 Thrombectomy & stent 3/25/2021 Thrombectomy 4/11/2021
COVID19 VACCINE	MODERNA	1195632-1	65+ years	15-30 days	right sided pleuritic chest pain started 04/11/2021.
COVID19 VACCINE	MODERNA	1196238-1	60-64 years	15-30 days	Pt complained of dizziness for 2 weeks prior to hospitalization 4/10/2021, and passed out 6 times in the 2 days prior to admission. Upon admission was found to have acute pulmonary embolism. Physician requested VAERS report.
COVID19 VACCINE	MODERNA	1198116-1	30-39 years	15-30 days	pulmonary embolism
COVID19 VACCINE	MODERNA	1202583-1	30-39 years	15-30 days	4/12/21 Patient presented to the emergency room with left side intermittent chest pain x1 week. Patient reports ""feels like heart beating out of chest"" yesterday. Workup was consistent with pulmonary embolism. Patient was admitted and Lovenox for pulmonary embolism treatment was started. Pain controlled, hypertension controlled.""
COVID19 VACCINE	MODERNA	1202649-1	65+ years	15-30 days	Blood clots then death
COVID19 VACCINE	MODERNA	1203313-1	40-49 years	15-30 days	PT EXP SHORTNESS OF BREATH AND CHEST PAIN; SELF REFERRED TO ER. D-DIMER ELEVATED. CHEST CTA SHOWS SOLITARY RIGHT UPPER LOBE PULMONARY ARTERY PULMONARY EMBOLISM. BILATERAL LOWER EXTREMITY ULTRA SOUND SHOWS THROMBOSIS FEMURAL ARTERY NO PERSONAL OR FAMILY HISTORY OF BLOOD CLOTS AND NO HISTORY OF BLEEDING EPISODES OR LONG TRAVEL OR SEDENTARYNESS.

COVID19 VACCINE	MODERNA	1203334-1	65+ years	15-30 days	Dose 1 was administered;10 days prior to dose 2 patient began to have shortness of breath. Dose 2 was administered 3-23-21, Moderna Lot 006B21A. Severe SOB and left sided pain 3-23-21 @ 5:30pm/difficulty moving around. Sought treatment at Hospital on 3-25-21 as symptoms were increasing in severity/chest xray and CT revealed pulmonary embolisms in both lungs; Heparin was started/transported by ambulance to another hospital for clot removal. Decided not to do procedure and was kept on Heparin for 24 hours. Began Eliquis that Friday/symptoms began to resolve and was dc'd on Saturday.
COVID19 VACCINE	MODERNA	1203359-1	40-49 years	15-30 days	Arterial blood clot to the superior mesenteric artery resulting in ischemic necrosis of the small bowel.
COVID19 VACCINE	MODERNA	1204693-1	40-49 years	15-30 days	presents with progressively worsening dyspnea on exertion for the last few weeks, much worse over the last one day. Patient reports feeling fatigued, having cough, and feeling more short of breath for the last day, and has developed central chest pain which is pleuritic in the emergency department. She reports that the chest pain is 4/10 in severity and does not radiate. Her caregiver at bedside reports that the patient has had worsening dyspnea on exertion for the last 3 or so weeks. Of note, she becomes dyspneic with limited exertion, such as going up a flight of stairs, at baseline. She had a fever of 101.4 °F at home earlier today, but denies chills or diaphoresis. He had 1 episode of nonbloody vomiting earlier today. Denies nausea at this time. She received her second dose of the Moderna COVID vaccine yesterday, 4 weeks after the first. They note that approximately 5 years ago, she had a prolonged admission for which she was transferred to OHSU and was on ECMO for a time before making a nearly full recovery. She has had the baseline dyspnea on exertion since that time. Review of Systems Constitutional: Positive for fever and malaise/fatigue. Negative for chills. HENT: Negative for sore throat. Eyes: Negative for blurred vision. Respiratory: Positive for cough and shortness of breath. Negative for hemoptysis, sputum production and wheezing. Cardiovascular: Positive for chest pain. Gastrointestinal: Negative for abdominal pain, diarrhea and vomiting. Genitourinary: Negative for dysuria and frequency. Musculoskeletal: Negative for back pain. Skin: Negative for rash. Neurological: Positive for weakness. Negative for tingling, sensory change and focal weakness. Endo/Heme/Allergies: Does not bruise/bleed easily. Psychiatric/Behavioral: The patient is nervous/anxious. Past Medical History: Past Medical History: Diagnosis Date ? Developmental delay, moderate since birth Functional equivalent to 10-12 year old, no formal testing done otherwise. ? DVT (deep venous thrombosis) (HCC) 1/2016 while on ECMO ? Personal history of ECMO 1/2016 - ARDS after unknown viral illness Past Surgical History: Procedure Laterality Date ? LUNG BIOPSY Left 1995 Mass noted following an MVA, was benign ? MASS EXCISION Right 2006 Growth removed from right knee ? PROCEDURE N/A 1/20/2021 Procedure: LAPAROSCOPIC CHOLECYSTECTOMY; CHOLANGIOGRAMS; Service: Procedures; Laterality: N/A; POSSIBLE COMMON BILE DUCT ? PROCEDURE N/A 1/20/2021 Procedure: RIGID ESOPHAGOGASTRODUODENOSCOPY; Service: Procedures; Laterality: N/A; Medications administered in the ED: Medications doxycycline (VIBRAMYCIN) 100 mg in sodium chloride 0.9 % (NS) 100 mL IVPB (100 mg Intravenous New Bag 4/9/21 2235) ceftriaxone (ROCEPHIN) 1 g in 50 mL SNAP IVPB (0 g Intravenous Stopped 4/9/21 2234) Physical Examination: GEN: Very pleasant female sitting up in bed in NAD. Slightly anxious appearing. HENT: Moist mucous membranes. No posterior oropharyngeal erythema or exudates. NECK: Supple. No cervical or supraclavicular lymphadenopathy. CARDIOVASCULAR: Tachycardic rate and regular rhythm. No murmurs, rubs, or gallops. No pain with palpation of chest wall. PULM: Normal effort. No use of accessory muscles. Clear to auscultation bilaterally. No wheezes or crackles. ABD: Soft. Non tender. Non distended. EXT: No lower extremity edema. SKIN: No suspicious lesions noted on the exposed skin. EKG: 04/09/21 Rhythm: Sinus tachycardia Rate: 111 Axis: normal Intervals: normal Concern for possible inferior infarct noted, but felt less consistent with true ST depression Recent Imaging: Chest x-ray, 04/09/21:
COVID19 VACCINE	MODERNA	1205545-1	65+ years	15-30 days	Patient experienced shortness of breath a few days leading up to the adverse event. On the evening of March 11, 2021, he collapsed. An ambulance was called and he was taken to Emergency Room. He stayed there until the morning of March 12, 2021 when it was discovered that he had multiple blood clots in his lungs. At that time, he was air lifted to Hospital Intensive Care where he stayed until March 17, 2021. At that time, he was moved to Health Rehabilitation Hospital of where he stayed until March 27, 2021. First vaccination was on 01/22/2021; Second was on 02/17/2021.

COVID19 VACCINE	MODERNA	1205863-1	65+ years	15-30 days	Died from Pulmonary Embolism. No leg pain, no leg swelling to indicate DVT in leg. Also was thrombocytopenic at the time of emergency/ER visit/treatment. He suddenly complained of very bad chest pain, could hardly speak to tell symptoms. Immediate resuscitation was started by family member and 911 was called. Ambulance detected tech, tried to electroconvert, but was not successful. Chest compression and bagging was done until patient got the hospital. There full resuscitation effort. Unsuccessful. Troponin normal, D-dimer sky high.
COVID19 VACCINE	MODERNA	1206341-1	50-59 years	15-30 days	i suffered two DVT's in my left leg... These occurred 2.5 weeks after second Moderna vaccine. I have a history of DVT and PE 20 years ago....I am on Coumadin... Coumadin was considered a fail and now I am on Xarelto.
COVID19 VACCINE	MODERNA	1206927-1	60-64 years	15-30 days	burning sensation in the lung; had labored breathing,they found several clots in right leg and lungs; It was shiny and hard and calf blewup twice the size,they found several clots in right leg; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (had labored breathing,they found several clots in right leg and lungs) and THROMBOSIS (It was shiny and hard and calf blewup twice the size,they found several clots in right leg) in a 63-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 002B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Family history included Clot blood (Family history of clots; her father and his sister had clots after surgery). Concurrent medical conditions included Burning sensation. On 12-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-Apr-2021, the patient experienced PULMONARY EMBOLISM (had labored breathing,they found several clots in right leg and lungs) (seriousness criterion medically significant) and THROMBOSIS (It was shiny and hard and calf blewup twice the size,they found several clots in right leg) (seriousness criterion medically significant). On an unknown date, the patient experienced BURNING SENSATION (burning sensation in the lung). At the time of the report, PULMONARY EMBOLISM (had labored breathing,they found several clots in right leg and lungs), THROMBOSIS (It was shiny and hard and calf blewup twice the size,they found several clots in right leg) and BURNING SENSATION (burning sensation in the lung) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Ultrasound Doppler: several clots in right leg and lungs (abnormal) several clots in right leg and lungs. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. No concomitant products were reported. Patient was taken to the ER (emergency room). The physician suspected blood clots and treatment included was blood thinner. Patient reported that ""patient got ultrasound done on Monday, and they found several clots in right leg and lungs""; Sender's Comments: Based on the current available information which includes a strong temporal association between the use of the product and onset of the reported events, and excluding other etiologies, a causal relationship cannot be excluded""
COVID19 VACCINE	MODERNA	1206946-1	50-59 years	15-30 days	admitted to hospital on 3/25/21 for Cholelithiasis and during the workups had an Ultrasound - VL Lower Ext Veenous Duplex Bilateral study on 3/26/21.
COVID19 VACCINE	MODERNA	1207773-1	65+ years	15-30 days	2nd moderna vaccine was given to my dad on 02/26/2021 and on 03/15/2021 my dad was visiting me all day and he acted fine and normal. At the end of our visit between 8 & 9 pm we went to the store where he started to gasp for breath. He had to keep stopping and said he couldn't breath. I had him sit several times because I didn't know how bad it was. By the time we reached the doors to leave after a short trip he almost fell over and he became confused and said he couldn't breath. I had another customer get my dad a wheel chair close by while I called 911. The ambulance came quickly but at the hospital my dad went into cardiac arrest and his heart stopped 2 or 3 times and it had to be restarted. When I was able to get to the hospital my dad was on a ventilator and sedated. They had put him on medicine to blast the blood clots they had found. They said he had 2 very large blood clots with one on each lung. Later his kidneys started failing him and they said he would need to go on dialysis as soon as the next day. Later that night they told me my dads heart was shutting down and he had developed pneumonia. My dad died that night and I had to watch him take his last breath. If you want further information please contact Medical center would be the ones to contact for all information and my dad was in the critical care unit.
COVID19 VACCINE	MODERNA	1208261-1	30-39 years	15-30 days	Acute bilateral deep vein thrombosis and bilateral pulmonary emboli

COVID19 VACCINE	MODERNA	1208285-1	65+ years	15-30 days	Blood clot in brain caused stroke
COVID19 VACCINE	MODERNA	1209129-1	65+ years	15-30 days	Bad chest pains, palpitations and high blood pressure. Ct scan found two small clots (pulmonary embolism)
COVID19 VACCINE	MODERNA	1209149-1	65+ years	15-30 days	Note: Initial date is an estimate based on patient scheduled to get 2nd dose on 4/19. Patient with acute DVT noted. Note, per patient, he has a history of multiple DVT in the past and was prescribed to be on medication for this, which he stopped years ago. Patient placed on anticoagulation for acute DVT, seeing specialty to look for possible cause of hypercoagulability. Patient saw me first for diagnosis of acute DVT, so history prior to this is limited and based on patient's report.
COVID19 VACCINE	MODERNA	1209433-1	30-39 years	15-30 days	Diagnosed w/ left lung PE at hospital 4/2/2021
COVID19 VACCINE	MODERNA	1210452-1	60-64 years	15-30 days	immune mediated thrombocytopenia, anemia, pulmonary embolism, pulmonary infiltrates. treated with IVIG x 2 days and prednisone 120 mg daily. started on heparin drip.
COVID19 VACCINE	MODERNA	1210554-1	65+ years	15-30 days	Bilateral pulmonary embolisms requiring ICU admission. Patient presented to Emergency Room on 4/13/21 with presented to the ED with shortness of breath and chest pain. The patient notes that she developed shortness of breath, particularly with exertion, about 1 week prior to presentation. 2-3 days prior to presentation, she developed pleuritic chest pain on the right anterior chest. She denies any recent fevers, chills, weight changes, palpitations, cough, sputum production, abdominal pain, nausea, vomiting, diarrhea, constipation, lower extremity edema. She does note that she received her first dose of the COVID-19 vaccine on 3/16/2021 and was due for dose#2 on the day of admission. She denies a personal history of blood clots and denies current smoking, estrogen use, or recent surgery. She does note a history of blood clots in her sister, but she is unsure whether they were provoked or unprovoked. Patient required BiPAP on admission and was initiated on a heparin drip. Initial CT w/ some concern for R heart strain, however, echocardiogram showed no signs of R heart strain and she was hemodynamically stable. She was weaned from the BiPAP to Non-rebreather, and eventually nasal cannula. The heparin drip was transitioned to lovenox with plans to go home on a DOAC. Still hospitalized at time of event report.
COVID19 VACCINE	MODERNA	1210977-1	40-49 years	15-30 days	Lower right leg blood clot. Currently on Xarelto blood thinner.
COVID19 VACCINE	MODERNA	1212513-1	50-59 years	15-30 days	Pt reports after his vaccine he had mild symptoms on 3/24/21 the developed SOB and rapid heartbeat on 4/6/2021 and was admitted to the Hospital for blood clots. Pt was hospitalized from 4/6 to 4/9/21.
COVID19 VACCINE	MODERNA	1212528-1	65+ years	15-30 days	Pulmonary Embolism, Hospitalized, treated with TPA.
COVID19 VACCINE	MODERNA	1213364-1	65+ years	15-30 days	death Narrative: Patient received Moderna COVID #1 vaccine on 1/28/21. On 2/3/21, he was admitted to a facility for fever, weakness, chills and rigor. Noted history of B cell lymphoma not on chemotherapy at the time. He also had reports of productive cough with thick brown/green sputum. He was admitted to the hospital and given 1 round of methotrexate and Rituxan. Hospital course was complicated with bacteremia (given vancomycin and cefepime), A fib, AKI, HTN, neutropenia (received Neupogen), acute popliteal VT (unable to anticoagulated due to thrombocytopenia - platelets as low as 20). No bleeding issues noted. On 2/18/21, family opted to change his status to DNR with hospice/comfort care and he passed on 2/19/21. No autopsy results available. 22 days from date of vaccine to date of death.
COVID19 VACCINE	MODERNA	1213430-1	50-59 years	15-30 days	Patient reports being hospitalized April 8-10 with blood clots in her legs and lungs
COVID19 VACCINE	MODERNA	1213525-1	65+ years	15-30 days	Right lower extremity swelling/pain 4/13/21 Improved swelling of right lower extremity 4/14/21 Heparin 1,000 unit/ml 5,592 units IV (80 units/kg x 69.9 kg) daily 4/12/21 Eliquis 10 mg po BID 4/14/21 to 4/20/21 Eliquis 5 mg po BID 4/21/21
COVID19 VACCINE	MODERNA	1213966-1	65+ years	15-30 days	pulmonary embolus which occurred 3 weeks after her first moderna covid vaccine
COVID19 VACCINE	MODERNA	1214422-1	60-64 years	15-30 days	Blood clots in left leg, hip, bilateral lungs; treated with blood thinners; was admitted to hospital from 4/1-4/3; discharged to home, stable
COVID19 VACCINE	MODERNA	1214597-1	50-59 years	15-30 days	2nd dose Moderna administered on Feb 3rd, fatigue/ shortness of breath week of Feb 23rd, admitted to Hospital on March 1st, spent 18 days in ICU, developed Blood CLOTS which one attached to lung, blood clots in left leg as well, no family history of blood clots and no injuries to cause blood clots.
COVID19 VACCINE	MODERNA	1214679-1	18-29 years	15-30 days	cerebral venous sinus thrombosis
COVID19 VACCINE	MODERNA	1216365-1	65+ years	15-30 days	Pt was admitted to the hospital on 4/13/2021 after being found to be covid 19 positive. She reported fever, cough and chills. she was febrile 101.2 and tachycardic. She was discharged home on 4/15/2021 on xarelto 10mg for 30 day and decadron 6mg for 3 more days. She was given regeneron during her hospital stay. It was also noted that she had a superficial venous thrombosis of the right greater saphenous vein extending into the upper thigh to the upper calf.

COVID19 VACCINE	MODERNA	1218240-1	65+ years	15-30 days	Extensive DVT(blood clots) involving both legs-- initially with tachycardia dyspnea. Now on 10a meds. Likely to have disability or permanent damage. History of post-op DVT with PEs following shoulder surgery, subsequent placement of IVC filter.
COVID19 VACCINE	MODERNA	1218702-1	60-64 years	15-30 days	14 days after 2nd dose severe shortness of breath, fatigue, lightheaded, near syncope. Diagnosed with bilateral DVT and bilateral PE
COVID19 VACCINE	MODERNA	1219492-1	65+ years	15-30 days	large RUE DVT
COVID19 VACCINE	MODERNA	1220897-1	65+ years	15-30 days	pulmonary embolism; shortness of breath, shortness of breath was getting worse; Nausea; migraine; Myalgia; low grade fever; This spontaneous case was reported by a pharmacist (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (pulmonary embolism) and DYSPNOEA (shortness of breath, shortness of breath was getting worse) in a 67-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 047821A and 014M2A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Prostate cancer and Proctectomy. Concurrent medical conditions included Asthma, Hypertension (Controlled), Hypercholesterolemia (Controlled), Failed back surgery syndrome, Chronic back pain, Drug allergy (NSAIDs), Drug allergy (Fluconazole (Fluticasone)) and Drug allergy (Zipro). Concomitant products included SUMATRIPTAN (IMITREX [SUMATRIPTAN]) for Migraine, DENOSUMAB (PROLIA), ALBUTEROL [SALBUTAMOL], ALPRAZOLAM (XANAX), CELECOXIB (CELEBREX), RIVAROXABAN (XARELTO), TADALAFIL (CIALIS), CEFIXIME (FLEXERIL [CEFIXIME]), MAGNESIUM, ZONISAMIDE (ZONEGRAN), OXYCODONE, EZETIMIBE (ZETIA), PRAVASTATIN, RAMIPRIL and CARVEDILOL for an unknown indication. On 26-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 27-Mar-2021, the patient experienced MIGRAINE (migraine), MYALGIA (Myalgia) and PYREXIA (low grade fever). On 28-Mar-2021, the patient experienced NAUSEA (Nausea). On 29-Mar-2021, the patient experienced DYSPNOEA (shortness of breath, shortness of breath was getting worse) (seriousness criterion hospitalization). On 02-Apr-2021, the patient experienced PULMONARY EMBOLISM (pulmonary embolism) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 02-Apr-2021 to 05-Apr-2021 due to DYSPNOEA and PULMONARY EMBOLISM. On 28-Mar-2021, PYREXIA (low grade fever) had resolved. At the time of the report, PULMONARY EMBOLISM (pulmonary embolism), DYSPNOEA (shortness of breath, shortness of breath was getting worse), MIGRAINE (migraine), MYALGIA (Myalgia) and NAUSEA (Nausea) outcome was unknown. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 24-Mar-2021, Physical examination: normal (normal) no findings. On 27-Mar-2021, Body temperature: 37.8 degree Celsius (High) Self Test. In April 2021, Computerised tomogram: abnormal (abnormal) pulmonary embolism with CAT scan with dye, multiple pulmonary embolism in the lungs.. In April 2021, Fibrin D dimer: high (High) High. In April 2021, Ultrasound scan: negative (Negative) Negative. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter considered PULMONARY EMBOLISM (pulmonary embolism) and DYSPNOEA (shortness of breath, shortness of breath was getting worse) to be possibly related. No further causality assessments were provided for MIGRAINE (migraine), MYALGIA (Myalgia), PYREXIA (low grade fever) and NAUSEA (Nausea). Treatment medications included sumatriptan (for migraine), and prednisone and home nebulize albuterol (for asthma exacerbation). Company Comment: Very limited information regarding these events has been provided at this time. Further information has been requested. Based on the current available information and temporal association

COVID19 VACCINE	MODERNA	1220939-1	Unknown	15-30 days	<p>Acute cor pulmonale; problems breathing; experienced heart strongest beat; dizziness; Saddle embolism pulmonary art; This spontaneous case was reported by a consumer and describes the occurrence of PULMONARY EMBOLISM (Saddle embolism pulmonary art), COR PULMONALE ACUTE (Acute cor pulmonale), DYSPNOEA (problems breathing), PALPITATIONS (experienced heart strongest beat) and DIZZINESS (dizziness) in a 57-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 003A21A) for COVID-19 vaccination. The patient's past medical history included No adverse event (No reported medical history). Concomitant products included LEVOTHYROXINE SODIUM (SYNTHROID) and ERENUMAB (AIMOVIG [ERENUMAB]) for an unknown indication. On 06-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 28-Mar-2021, the patient experienced PULMONARY EMBOLISM (Saddle embolism pulmonary art) (seriousness criteria hospitalization and life threatening), DYSPNOEA (problems breathing) (seriousness criterion hospitalization), PALPITATIONS (experienced heart strongest beat) (seriousness criterion hospitalization) and DIZZINESS (dizziness) (seriousness criterion hospitalization). On an unknown date, the patient experienced COR PULMONALE ACUTE (Acute cor pulmonale) (seriousness criteria hospitalization and life threatening). The patient was hospitalized from 28-Mar-2021 to 31-Mar-2021 due to COR PULMONALE ACUTE, DIZZINESS, DYSPNOEA, PALPITATIONS and PULMONARY EMBOLISM. On 31-Mar-2021, PULMONARY EMBOLISM (Saddle embolism pulmonary art) outcome was unknown. At the time of the report, COR PULMONALE ACUTE (Acute cor pulmonale), DYSPNOEA (problems breathing), PALPITATIONS (experienced heart strongest beat) and DIZZINESS (dizziness) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. After 2 weeks of vaccination, the patient started to experienced heart strongest beat, problems to breathing and dizziness. On 28 MAR 2021 she felt this symptom and she thought ""something is going bad"" and has to be hospitalized on intensive care unit (ICU) from 28MAR2021 to 31MAR2021 (4 days). They diagnosticated ""saddle embolism pulmonary art with acute cor pulmonale"". They found several clots in both lungs and one big clot/ one large clot in the pulmonary artery. Pulmonary embolism between lungs. Treatment information was not provided. Vaccination second dose was recommended. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.""</p>
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COVID19 VACCINE	MODERNA	1221044-1	Unknown	15-30 days	<p>Blood clot in the right leg; Blood clot in the lungs; Blood clot in the hip; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clot in the hip), THROMBOSIS (Blood clot in the right leg) and PULMONARY EMBOLISM (Blood clot in the lungs) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. Unknown and 015L20A) for COVID-19 vaccination. The patient's past medical history included No adverse event (No reported medical history). On 06-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. In February 2021, the patient experienced THROMBOSIS (Blood clot in the hip) (seriousness criteria hospitalization and medically significant). In March 2021, the patient experienced THROMBOSIS (Blood clot in the right leg) (seriousness criteria hospitalization and medically significant) and PULMONARY EMBOLISM (Blood clot in the lungs) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on 16-Mar-2021 due to PULMONARY EMBOLISM, THROMBOSIS, THROMBOSIS At the time of the report, THROMBOSIS (Blood clot in the hip), THROMBOSIS (Blood clot in the right leg) and PULMONARY EMBOLISM (Blood clot in the lungs) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Patient states that 2-3 weeks after receiving the second shot they had a blood clot in the hip and a week later they had a blood clot in the right leg and in the lungs. Patient reports they had to be hospitalized for two nights, in the Medical City Fort Worth Hospital. Patient states they do not have any history of blood clots. Patient mentioned reading online, in forums, that people had taken Pfizer and Moderna vaccines and two weeks after had blood clots and ended in the hospital. Based on the current available information and temporal association between the use of the product and the start dates of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start dates of the events, a causal relationship cannot be excluded.</p>
COVID19 VACCINE	MODERNA	1221916-1	65+ years	15-30 days	<p>blood clot in his brain; Patient collapsed on the floor at night 2 days after receiving 2nd dose; brain was dead; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of BRAIN DEATH (brain was dead), CEREBRAL THROMBOSIS (blood clot in his brain) and LOSS OF CONSCIOUSNESS (Patient collapsed on the floor at night 2 days after receiving 2nd dose) in an 83-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 0021B21A and 001821A) for COVID-19 vaccination. The patient's past medical history included No adverse event (no medical history reported). On 27-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 29-Mar-2021, the patient experienced LOSS OF CONSCIOUSNESS (Patient collapsed on the floor at night 2 days after receiving 2nd dose) (seriousness criterion hospitalization prolonged). On 30-Mar-2021, the patient experienced CEREBRAL THROMBOSIS (blood clot in his brain) (seriousness criteria death and hospitalization prolonged). The patient died on 08-Apr-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, LOSS OF CONSCIOUSNESS (Patient collapsed on the floor at night 2 days after receiving 2nd dose) outcome was unknown. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Mar-2021, X-ray: blood clot (Positive) x-rays revealed blood clot in his brain. No concomitant medications were reported. After the 2nd dose, On 29Mar2021, at night, he collapsed on the floor and was taken at the hospital on same night by ambulance. So he was hospitalized on 30Mar2021 and upon doing tests and x-rays, they found blood clot in his brain. He stayed in hospital through out and transferred to hospice center on 06Apr2021 where he passed away on 08Apr2021. His brain was dead and never recovered from the clot. Unknown treatment medications were given at the hospital. Very limited information regarding these events have been provided at this time. No further information is expected.; Sender's Comments: Very limited information regarding these events have been provided at this time. No further information is expected.; Reported Cause(s) of Death: Unknown cause of death</p>
COVID19 VACCINE	MODERNA	1223056-1	60-64 years	15-30 days	<p>My wife started to fall and pass out had no strength to get up this happened two to three times cinch she got the shot the last time she past out in the shower and i rushed her to hospital were she pasted away from blood clots to the right side of the neck and stated bleed on the brain</p>

COVID19 VACCINE	MODERNA	1235666-1	Unknown	15-30 days	<p>Patient got scared and did not get his second dose; tried to urinate and could not; passed a clot with some drops of blood; This spontaneous case was reported by a consumer and describes the occurrence of URINARY RETENTION (tried to urinate and could not) and HAEMORRHAGE URINARY TRACT (passed a clot with some drops of blood) in a 73-year-old male patient who received mRNA-1273 (batch no. 024M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Tumor (Malignancy in the tubular tumor in Penis) and Bladder operation (in past 3 months). Concurrent medical conditions included Diabetes and Hypertension. Concomitant products included METFORMIN, LISINAPRIL, AMLODIPINE and ESCITALOPRAM for an unknown indication, PRAVASTATIN SODIUM (PRAVASTATIN NA). On 16-Mar-2021, the patient received first dose of mRNA-1273 (Intramuscular) 1 dosage form. On 31-Mar-2021, the patient experienced URINARY RETENTION (tried to urinate and could not) (seriousness criterion medically significant) and HAEMORRHAGE URINARY TRACT (passed a clot with some drops of blood) (seriousness criterion medically significant). On 13-Apr-2021, the patient experienced PRODUCT DOSE OMISSION ISSUE (Patient got scared and did not get his second dose). At the time of the report, URINARY RETENTION (tried to urinate and could not), HAEMORRHAGE URINARY TRACT (passed a clot with some drops of blood) and PRODUCT DOSE OMISSION ISSUE (Patient got scared and did not get his second dose) outcome was unknown. The action taken with mRNA-1273 (Intramuscular) was unknown. Treatment medication was not reported. Based on the current available information and the temporal association between the product use and the start of the events a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and the temporal association between the product use and the start of the events a causal relationship cannot be excluded.</p>
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COVID19 VACCINE	MODERNA	1235687-1	40-49 years	15-30 days	<p>Memory lapse, difficulty with memory recall; Confused; Blood clots; Cerebral Ischemic Attack; Brain Fog; Headache; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of MEMORY IMPAIRMENT (Memory lapse, difficulty with memory recall), CONFUSIONAL STATE (Confused), THROMBOSIS (Blood clots) and TRANSIENT ISCHAEMIC ATTACK (Cerebral Ischemic Attack) in a 49-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 046A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Heart valve operation. Concomitant products included WARFARIN SODIUM (COUMADIN) for an unknown indication. On 12-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 10-Apr-2021, the patient experienced MEMORY IMPAIRMENT (Memory lapse, difficulty with memory recall) (seriousness criterion hospitalization), CONFUSIONAL STATE (Confused) (seriousness criterion hospitalization), THROMBOSIS (Blood clots) (seriousness criterion hospitalization) and TRANSIENT ISCHAEMIC ATTACK (Cerebral Ischemic Attack) (seriousness criterion hospitalization). On 15-Apr-2021, the patient experienced FEELING ABNORMAL (Brain Fog) and HEADACHE (Headache). The patient was hospitalized from 10-Apr-2021 to 12-Apr-2021 due to CONFUSIONAL STATE, MEMORY IMPAIRMENT, THROMBOSIS and TRANSIENT ISCHAEMIC ATTACK. At the time of the report, MEMORY IMPAIRMENT (Memory lapse, difficulty with memory recall), FEELING ABNORMAL (Brain Fog) and HEADACHE (Headache) had not resolved and CONFUSIONAL STATE (Confused), THROMBOSIS (Blood clots) and TRANSIENT ISCHAEMIC ATTACK (Cerebral Ischemic Attack) had resolved. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Apr-2021, Computerised tomogram: abnormal (abnormal) revealed blood clots. On 10-Apr-2021, International normalised ratio: low (Low) Low. On 10-Apr-2021, Magnetic resonance imaging: abnormal (abnormal) revealed blood clots. On 15-Apr-2021, International normalised ratio: low (Low) Low. It was reported that the patient still has difficulty with memory recall, brain fog, headache, and still having trouble with low INR. The patient did not have any side effects after the first dose. Treatment for the events included Levonox injections and Coumadin (increased dose). Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, excluding other etiologies causal relationship cannot be excluded. Headache is consistent with the product known safety profile.; Sender's Comments: Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, excluding other etiologies causal relationship cannot be excluded. Headache is consistent with the product known safety profile.</p>
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COVID19 VACCINE	MODERNA	1245430-1	65+ years	15-30 days	<p>Veins was outside and sore; really big and sore red area; really big and sore red area; all the veins in his R leg was protuberate; two blood clot; DGThrombosis; Felt terrible; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (two blood clot) and THROMBOSIS (DGThrombosis) in a 77-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 016M20A and Unknown) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Leg injury (severe damage to right leg, hit by ""protellier"" small airplane.) in 1977, Surgery (""many surgeries"" ) and Clot blood. On 11-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 12-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 12-Mar-2021, the patient experienced MALAISE (Felt terrible). On 13-Mar-2021, the patient experienced THROMBOSIS (two blood clot) (seriousness criterion medically significant), THROMBOSIS (DGThrombosis) (seriousness criterion medically significant), VASCULAR PAIN (Veins was outside and sore), ERYTHEMA (really big and sore red area), PAIN IN EXTREMITY (really big and sore red area) and VEIN DISORDER (all the veins in his R leg was protuberate). At the time of the report, THROMBOSIS (two blood clot), THROMBOSIS (DGThrombosis), MALAISE (Felt terrible), VASCULAR PAIN (Veins was outside and sore), ERYTHEMA (really big and sore red area), PAIN IN EXTREMITY (really big and sore red area) and VEIN DISORDER (all the veins in his R leg was protuberate) outcome was unknown. Not Provided Concomitant medication included unspecified statin for high cholesterol. The patient reported that he is retired. He reported that his leg is functioning well, he has only one of the three arteries in the legs and many damaged veins. Treatment medication included Seroto to treat the blood clots. Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. This case was linked to MODERNATX, INC.-MOD-2021-077978 (E2B Linked Report).; Sender's Comments: Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. MODERNATX, INC.-MOD-2021-077978: ""</p>
COVID19 VACCINE	MODERNA	1245440-1	Unknown	15-30 days	<p>blood clots; his arm felt sore, almost like he had just received the vaccine; doctor thinks it has something to do with the heart; low blood pressure; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (blood clots) in a 64-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 24-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 08-Apr-2021, the patient experienced THROMBOSIS (blood clots) (seriousness criterion hospitalization), PAIN IN EXTREMITY (his arm felt sore, almost like he had just received the vaccine), CARDIAC DISORDER (doctor thinks it has something to do with the heart) and HYPOTENSION (low blood pressure). The patient was hospitalized on 08-Apr-2021 due to THROMBOSIS. At the time of the report, THROMBOSIS (blood clots), PAIN IN EXTREMITY (his arm felt sore, almost like he had just received the vaccine) and CARDIAC DISORDER (doctor thinks it has something to do with the heart) had not resolved and HYPOTENSION (low blood pressure) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant product use was not provided. On 08 Apr 2021, the patient's arm felt sore, ""almost like he had just received the vaccine"". He went to urgent care, and they sent him to the hospital and he was admitted. The patient said his doctor thinks the blood clots had something to do with the heart. The patient thought it had to do with the vaccine because he has ""always been healthy"" and never had any heart problems. The patient was still in the hospital at the time of this report. Treatment information was not provided. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Doctor thinks ""thrombosis"" has something to do with the heart""</p>

COVID19 VACCINE	MODERNA	1245476-1	65+ years	15-30 days	<p>Blood clots; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (Blood clots) in an 82-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 013A21A and 031L209) for COVID-19 vaccination. Concurrent medical conditions included Cancer (The patient was in recovery from cancer). On 03-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. In March 2021, the patient experienced THROMBOSIS (Blood clots) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Blood clots) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In March 2021, Computerised tomogram: blood clots (abnormal) Blood clots. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications were not provided. Description: The patient developed blood clots (medically significant) two weeks after receiving his second dose of the vaccine. The patient was in recovery from cancer and was required to have computerized tomography (CT) scans. He had a computerized tomography (CT) scan within two weeks of taking his second dose and the blood clots were discovered. The patient had never had blood clots before. The patient had already been in contact with his oncologist and was prescribed apixaban. The patient received both scheduled doses of mRNA-1273 prior to the event, therefore action taken with the drug in response to the event is not applicable.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p>
COVID19 VACCINE	MODERNA	1249568-1	30-39 years	15-30 days	<p>blood clot on the left leg; blood clot on the right leg; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (blood clot on the right leg) and THROMBOSIS (blood clot on the left leg) in a 30-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 038321A) for COVID-19 vaccination. The patient's past medical history included No adverse event (no medical history reported). On 11-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 08-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 05-Apr-2021, the patient experienced THROMBOSIS (blood clot on the right leg) (seriousness criterion medically significant). On 12-Apr-2021, the patient experienced THROMBOSIS (blood clot on the left leg) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (blood clot on the right leg) and THROMBOSIS (blood clot on the left leg) outcome was unknown. Not Provided The patient has not provided with any concomitant medication. No treatment medications are listed. Company Comment Based on the current available information which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-043122 (E2B Linked Report). Reporter did not allow further contact; Sender's Comments: US-MODERNATX, INC.-MOD-2021-043122:1st dose</p>

COVID19 VACCINE	MODERNA	1249614-1	50-59 years	15-30 days	<p>Thrombosis of inferior mesenteric and splenic vein/Severe Abdominal pain; Thrombosis of inferior mesenteric and splenic vein/ severe abdominal pain; Headache; Nausea; This spontaneous case was reported by a nurse (subsequently medically confirmed) and describes the occurrence of SPLENIC VEIN THROMBOSIS (Thrombosis of inferior mesenteric and splenic vein/ severe abdominal pain) and MESENTERIC VEIN THROMBOSIS (Thrombosis of inferior mesenteric and splenic vein/Severe Abdominal pain) in a 59-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 025L20A and 011B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No recorded medical history). On 22-Dec-2020, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 19-Jan-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 19-Jan-2021, the patient experienced HEADACHE (Headache) and NAUSEA (Nausea). On 27-Jan-2021, the patient experienced SPLENIC VEIN THROMBOSIS (Thrombosis of inferior mesenteric and splenic vein/ severe abdominal pain) (seriousness criteria hospitalization prolonged and medically significant) and MESENTERIC VEIN THROMBOSIS (Thrombosis of inferior mesenteric and splenic vein/Severe Abdominal pain) (seriousness criteria hospitalization and medically significant). The patient was hospitalized for 1 day due to SPLENIC VEIN THROMBOSIS. At the time of the report, SPLENIC VEIN THROMBOSIS (Thrombosis of inferior mesenteric and splenic vein/ severe abdominal pain), MESENTERIC VEIN THROMBOSIS (Thrombosis of inferior mesenteric and splenic vein/Severe Abdominal pain), HEADACHE (Headache) and NAUSEA (Nausea) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Jan-2021, Computerised tomogram: thrombosis of inferior mesenteric and splenic vein (abnormal) Thrombosis of inferior mesenteric and Splenic vein. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. The patient experienced severe abdominal pain and went to Emergency room and CT Scan and lab investigations were done. She was given. The patient stayed for 24 hours in Emergency room. The patient received 1st dose of Moderna vaccine on 22 Dec2021 and no symptom after vaccine administration. Treatment for the event included prescribed apixaban for 6 months and heparin. The patient received both scheduled doses of mRNA-1273 prior to the event; therefore, action taken with the drug in response to the event is not applicable. Company Comment: Based on the current available information and temporal association between the use of the product and the start dates of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start dates of the events, a causal relationship cannot be excluded.</p>
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COVID19 VACCINE	MODERNA	1249671-1	65+ years	15-30 days	<p>they did ultrasound and found a blood clot in her right leg behind the knee; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEEP VEIN THROMBOSIS (they did ultrasound and found a blood clot in her right leg behind the knee) in a 76-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 031L20A) for COVID-19 vaccination. Concurrent medical conditions included Hypertension. Concomitant products included LIRAGLUTIDE (VICTOZA) and INSULIN GLARGINE (TOUJEO) for an unknown indication. On 25-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .5 milliliter. On 12-Apr-2021, the patient experienced DEEP VEIN THROMBOSIS (they did ultrasound and found a blood clot in her right leg behind the knee) (seriousness criterion medically significant). At the time of the report, DEEP VEIN THROMBOSIS (they did ultrasound and found a blood clot in her right leg behind the knee) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 12-Apr-2021, Ultrasound scan: found a blood clot in her right leg behind the knee (abnormal) found a blood clot in her right leg behind the knee. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment included xarelto 15mg. Concomitant medication included BP medicine. Her right leg started swelling and turned red a week ago(10Apr2021). She went to the doctor on 12Apr2021 and they did ultrasound and found a blood clot in her right leg behind the knee (12Apr2021). She is scheduled to get 2nd dose on 22Apr2021. She never had blood clot before so wanted to report it. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested</p>
COVID19 VACCINE	MODERNA	1249678-1	Unknown	15-30 days	<p>Left lung is beginning to hurt again; chest is killing him; can barely walk; pain all over; the knot on the arm is blood clot; knot under the skin on his arm; painful knot under the skin; nauseated; kept vomiting all the next day, threw up about 20 times; This spontaneous case was reported by a patient and describes the occurrence of THROMBOSIS (the knot on the arm is blood clot) in a 45-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 007B21A and 027A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Broken bones. Concurrent medical conditions included Autoimmune disorder in September 2020. On 18-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 15-Apr-2021, the patient experienced NAUSEA (nauseated) and VOMITING (kept vomiting all the next day, threw up about 20 times). On 18-Apr-2021, the patient experienced SKIN MASS (knot under the skin on his arm) and PAIN OF SKIN (painful knot under the skin). On 19-Apr-2021, the patient experienced THROMBOSIS (the knot on the arm is blood clot) (seriousness criterion medically significant). On 20-Apr-2021, the patient experienced PULMONARY PAIN (Left lung is beginning to hurt again), CHEST DISCOMFORT (chest is killing him), GAIT DISTURBANCE (can barely walk) and PAIN (pain all over). On 17-Apr-2021, NAUSEA (nauseated) and VOMITING (kept vomiting all the next day, threw up about 20 times) had resolved. At the time of the report, THROMBOSIS (the knot on the arm is blood clot), PULMONARY PAIN (Left lung is beginning to hurt again), CHEST DISCOMFORT (chest is killing him), GAIT DISTURBANCE (can barely walk), SKIN MASS (knot under the skin on his arm), PAIN OF SKIN (painful knot under the skin) and PAIN (pain all over) outcome was unknown. No concomitant medications were reported. Treatment for the events included Elquis and I.V heparin. This case was linked to MOD-2021-081600 (Patient Link); Sender's Comments: Based on the information provided which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. Nausea and vomiting are consistent with the product safety profile.</p>

COVID19 VACCINE	MODERNA	1257204-1	30-39 years	15-30 days	<p>Patient began experiencing pain and difficulty walking on Tuesday, March 23. Later that afternoon she was taken to an Urgent care, who sent her to the ER for evaluation. She was diagnosed with a very large blood clot in her leg, spanning from just above the knee to her groin area. They admitted her and began treating her with blood thinners. While undergoing that treatment, her heart stopped 3 times and she had to be resuscitated. They discovered a pulmonary embolism. While removing a large clot from her lungs, the doctor found that her lungs were riddled with hundreds of tiny blood clots. They also said that she was bleeding internally, very heavily, from an unknown location. In all, they gave her 20 units of blood, and none of it stayed in her veins. The doctor said it seemed to just disintegrate. At that point, her brain and organs had begun shutting down and family made the decision to remove her from life support. She passed away Thursday evening, March 25, 2021.</p>
COVID19 VACCINE	MODERNA	1261499-1	65+ years	15-30 days	<p>multiple pulmonary emboli; could barely breath; fatigue; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (multiple pulmonary emboli) and DYSPNOEA (could barely breath) in a 68-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 062G20A and 027L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Gallbladder removal on 25-Mar-2021. On 14-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 11-Feb-2021, the patient experienced FATIGUE (fatigue). On 27-Mar-2021, the patient experienced PULMONARY EMBOLISM (multiple pulmonary emboli) (seriousness criteria hospitalization prolonged, medically significant and life threatening) and DYSPNOEA (could barely breath) (seriousness criteria hospitalization prolonged, medically significant and life threatening). The patient was hospitalized for 3 days due to DYSPNOEA and PULMONARY EMBOLISM. On 13-Feb-2021, FATIGUE (fatigue) had resolved. At the time of the report, PULMONARY EMBOLISM (multiple pulmonary emboli) and DYSPNOEA (could barely breath) outcome was unknown. The doctors believed that her diagnosis was not a common side effect from the surgery and believed that the vaccine contributed to the diagnosis. She was treated with apixaban, omeprazole and aspirin 81mg (once daily). The patient is scheduled to visit a hematologist after 6 months. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested This case was linked to MOD-2021-081407 (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested MOD-2021-081407:Crosslinked case; Dose 1</p>

COVID19 VACCINE	MODERNA	1261538-1	50-59 years	15-30 days	<p>Blood clots; Gangrene; Missed her second dose as the hospital where the patient was admitted did not have Moderna vaccine; patient was sent to rehabilitation center; surgery (a leg was amputated); two clots were removed; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (Blood clots), THROMBECTOMY (two clots were removed), GANGRENE (Gangrene) and LEG AMPUTATION (surgery (a leg was amputated)) in a 50-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 025J20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Clot blood (blood clots in heart and lungs for last 15 years) and Thrombectomy (40 clots removed from heart and lungs from past 15 years). Concurrent medical conditions included Systemic lupus erythematosus (bad lupus). On 15-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 10-Feb-2021, the patient experienced THROMBOSIS (Blood clots) (seriousness criteria hospitalization and medically significant). On 01-Mar-2021, the patient experienced THROMBECTOMY (two clots were removed) (seriousness criterion hospitalization prolonged) and LEG AMPUTATION (surgery (a leg was amputated)) (seriousness criterion hospitalization prolonged). On 12-Mar-2021, the patient experienced REHABILITATION THERAPY (patient was sent to rehabilitation center). On an unknown date, the patient experienced GANGRENE (Gangrene) (seriousness criterion hospitalization prolonged) and PRODUCT ADMINISTRATION INTERRUPTED (Missed her second dose as the hospital where the patient was admitted did not have Moderna vaccine). The patient was hospitalized on 10-Feb-2021 due to THROMBOSIS, then on 27-Feb-2021 due to LEG AMPUTATION and THROMBECTOMY. The patient was treated with Surgery for Gangrene. On 01-Mar-2021, THROMBECTOMY (two dots were removed) and LEG AMPUTATION (surgery (a leg was amputated)) had resolved. At the time of the report, THROMBOSIS (Blood clots), PRODUCT ADMINISTRATION INTERRUPTED (Missed her second dose as the hospital where the patient was admitted did not have Moderna vaccine) and REHABILITATION THERAPY (patient was sent to rehabilitation center) outcome was unknown and GANGRENE (Gangrene) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. As per the patient's doctor, it was too late and dangerous to remove clots from the patient's leg and eventually, the doctor had to amputate the patient's leg because of gangrene. No concomitant medications were reported. Company comment: Based on current available information and the temporal association between product use and het start date of the events a causal relationship cannot be excluded.; Sender's Comments: Based on current available information and the temporal association between product use and het start date of the events a causal relationship cannot be excluded.</p>
COVID19 VACCINE	MODERNA	1261541-1	Unknown	15-30 days	<p>Venous thromboembolism; This spontaneous case was reported by a pharmacist (subsequently medically confirmed) and describes the occurrence of EMBOLISM VENOUS (Venous thromboembolism) in a 49-year-old female patient who received mRNA-1273 for COVID-19 vaccination. Co-suspect product included non-company product ORAL CONTRACEPTIVE NOS for Birth control. No Medical History information was reported. On 11-Mar-2021, the patient received first dose of mRNA-1273 (Intramuscular) 1 dosage form. On an unknown date, the patient started ORAL CONTRACEPTIVE NOS (Oral) at an unspecified dose. On 08-Apr-2021, the patient experienced EMBOLISM VENOUS (Venous thromboembolism) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 08-Apr-2021 to 12-Apr-2021 due to EMBOLISM VENOUS. At the time of the report, EMBOLISM VENOUS (Venous thromboembolism) outcome was unknown. The action taken with mRNA-1273 (Intramuscular) was unknown. For mRNA-1273 (Intramuscular), the reporter considered EMBOLISM VENOUS (Venous thromboembolism) to be unlikely related. Treatment medications included anticoagulant therapy. Limited information regarding the event has been provided at this time and a causal relationship cannot be excluded. Assessment is confounded by the reported use of oral contraceptive.; Sender's Comments: Limited information regarding the event has been provided at this time and a causal relationship cannot be excluded. Assessment is confounded by the reported use of oral contraceptive.</p>

COVID19 VACCINE	MODERNA	1264528-1	65+ years	15-30 days	My mom was very ill with fever like symptoms following her first vaccination on January 26th. The symptoms were even worse after her second vaccination March 2nd and included muscle cramping in her legs. Once she was recovered she only had a persistent cough which she attributed to allergies as the pollen count had been high. In the early morning hours of March 19th she was having difficulty breathing and chest pains. She was rushed to the emergency room where she subsequently died of cardio pulmonary embolism which the coroner indicated began within three weeks of her death.
COVID19 VACCINE	MODERNA	1272201-1	65+ years	15-30 days	Pulmonary embolism; died - autopsy showed multiple blood clots all over his body - pelvic area, hearts,arteries, lungs; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (died - autopsy showed multiple blood clots all over his body - pelvic area, hearts,arteries, lungs) and PULMONARY EMBOLISM (Pulmonary embolism) in an 83-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 039A21A and 003A21A) for COVID-19 vaccination. Concurrent medical conditions included Diabetes, Prostate cancer and Memory loss. Concomitant products included METFORMIN for Diabetes. On 05-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 04-Apr-2021, the patient experienced THROMBOSIS (died - autopsy showed multiple blood clots all over his body - pelvic area, hearts,arteries, lungs) (seriousness criterion death). On an unknown date, the patient experienced PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criterion death). The patient died on 04-Apr-2021. The reported cause of death was Pulmonary embolism. An autopsy was performed. The autopsy-determined cause of death was multiple blood clots. Action taken with mRNA-1273 in response to the event was not applicable Other concomitant medications were reported included unspecified medications for memory loss and diabetes. No treatment information was provided.; Sender's Comments: This is an 83-year-old, male patient who received mRNA-1273 Vaccine who experienced multiple thrombosis and died, 2 days after receiving second dose of vaccine. Medical history includes Diabetes, and Prostate cancer. Conmeds including some unspecified medications for memory loss and diabetes. The autopsy-determined cause of death was multiple blood clots. Very limited information has been reported at this time. Further information is expected,; Reported Cause(s) of Death: Pulmonary embolism; Autopsy-determined Cause(s) of Death: multiple blood clots

COVID19 VACCINE	MODERNA	1276772-1	50-59 years	15-30 days	<p>blood in her urine with clots; felt bad like the flu; went to sleep and woke up dizzy; buzzing in her ears; she feels with altitude sickness; Plugged ears; tiredness; nausea; headache; This spontaneous case was reported by a consumer and describes the occurrence of HAEMORRHAGE URINARY TRACT (blood in her urine with clots) in a 56-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No patient medical history reported. Concomitant products included METOPROLOL for an unknown indication. On 02-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 23-Apr-2021, the patient experienced HAEMORRHAGE URINARY TRACT (blood in her urine with clots) (seriousness criterion medically significant), INFLUENZA LIKE ILLNESS (felt bad like the flu), DIZZINESS (went to sleep and woke up dizzy), TINNITUS (buzzing in her ears), HYPOBARISM (she feels with altitude sickness), EAR DISCOMFORT (Plugged ears), FATIGUE (tiredness), NAUSEA (nausea) and HEADACHE (headache). At the time of the report, HAEMORRHAGE URINARY TRACT (blood in her urine with clots), INFLUENZA LIKE ILLNESS (felt bad like the flu), DIZZINESS (went to sleep and woke up dizzy), TINNITUS (buzzing in her ears), HYPOBARISM (she feels with altitude sickness), EAR DISCOMFORT (Plugged ears), FATIGUE (tiredness), NAUSEA (nausea) and HEADACHE (headache) outcome was unknown. Additional concomitant medications included reflux medication when needed and asthma medication when needed. This case concerns a 56-year-old female with a serious unexpected event of hemorrhage urinary tract, and nonserious unexpected Influenza like illness, dizziness, tinnitus, ear discomfort, hypobarism, and expected headache, fatigue, nausea. Hemorrhage urinary tract latency 22 days after first dose mRNA-1273. Event outcomes unknown. Based on current available information and temporal association between use of the product and the start date of the event, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-090443, US-MODERNATX, INC.-MOD-2021-090371 (E2B Linked Report); Sender's Comments: This case concerns a 56-year-old female with a serious unexpected event of hemorrhage urinary tract, and nonserious unexpected Influenza like illness, dizziness, tinnitus, ear discomfort, hypobarism, and expected headache, fatigue, nausea. Hemorrhage urinary tract latency 22 days after first dose mRNA-1273. Event outcomes unknown. Based on current available information and temporal association between use of the product and the start date of the event, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-090443:Dose 1 US-MODERNATX, INC.-MOD-2021-090371:Son's case</p>
COVID19 VACCINE	MODERNA	1284721-1	50-59 years	15-30 days	<p>Superficial blood clot; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (Superficial blood clot) in a 58-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 014C21A and 018B21A) for COVID-19 vaccination. No Medical History information was reported. On 25-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 23-Apr-2021, the patient experienced THROMBOSIS (Superficial blood clot) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Superficial blood clot) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 24-Apr-2021, Ultrasound scan: abnormal (abnormal) Ultrasound of left arm was done and determined a blood clot in that arm.. Patient went to the emergency room on 24 Apr 2021, approximately 7 pm. The patient was a healthy individual and used to do bike ride 11 miles per day with average speed 16mph. He did bike ride the evening of his second covid shot. No relevant concomitant medications were reported. Treatment information included anti-inflammatory medicine. Action taken with mRNA-1273 in response to the events was not applicable. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 26-Apr-2021: Additional information was received on 26 Apr 2021. Added lab data and treatment; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

COVID19 VACCINE	MODERNA	1288539-1	Unknown	15-30 days	Multiple Pulmonary Emboli on both sides of the lungs\ multiple Pulmonary emboli like a spray of blood clots in the lungs; had trouble breathing; sharp pain on the right side of the chest; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Multiple Pulmonary Emboli on both sides of the lungs\ multiple Pulmonary emboli like a spray of blood clots in the lungs), DYSPNOEA (had trouble breathing) and CHEST PAIN (sharp pain on the right side of the chest) in a 75-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 020B21A and 007C21A) for COVID-19 vaccination. The patient's medical history was not provided. Concomitant products included SIMVASTATIN for an unknown indication. On 28-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 20-Apr-2021, the patient experienced PULMONARY EMBOLISM (Multiple Pulmonary Emboli on both sides of the lungs\ multiple Pulmonary emboli like a spray of blood clots in the lungs) (seriousness criteria hospitalization and medically significant), DYSPNOEA (had trouble breathing) (seriousness criterion hospitalization) and CHEST PAIN (sharp pain on the right side of the chest) (seriousness criterion hospitalization). The patient was hospitalized from 20-Apr-2021 to 21-Apr-2021 due to CHEST PAIN, DYSPNOEA and PULMONARY EMBOLISM. At the time of the report, PULMONARY EMBOLISM (Multiple Pulmonary Emboli on both sides of the lungs\ multiple Pulmonary emboli like a spray of blood clots in the lungs), DYSPNOEA (had trouble breathing) and CHEST PAIN (sharp pain on the right side of the chest) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 21-Apr-2021, Computerised tomogram: multiple pulmonary emboli CT scan showed multiple Pulmonary emboli like a spray of blood clots. Patient was taken to emergency room (ER) on 20-APR-2021. Patient was discharged next day given prescription of blood thinners and pain medications. Action taken with mRNA-1273 in response to the events was not applicable. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1290733-1	65+ years	15-30 days	Found unresponsive but still breathing at assisted living. Sent by ambulance to the hospital
COVID19 VACCINE	PFIZER\BIONTECH	0932091-1	50-59 years	15-30 days	Started severe belly pain and went to Emergency room and diagnosed with mesenteric vein thrombosis after the CT scan of the abdomen, treated with heparin drip, antibiotic and discharged with anticoagulant pills(Eliquis). I am not sure that it is because of the vaccine my doctors are also not sure about it, but I am sure that I am a healthy person without any health issues . I am working as registered nurse, our unit is for covid-19 patient's since march 2020 and I had covid -19 on August month and recovered after 3 weeks.
COVID19 VACCINE	PFIZER\BIONTECH	0938186-1	30-39 years	15-30 days	Heavy period with more bleeding. And cramping and multiple clots
COVID19 VACCINE	PFIZER\BIONTECH	0946900-1	40-49 years	15-30 days	Hospital Course: · Patient is a 43 y.o. female patient who originally presented to the hospital on 1/3/2021 due to Left lower extremity pain and swelling. Patient found to have extensive DVT of left lower extremity and started on heparin drip. Vascular was consulted and recommended thrombolysis. Patient was also seen by IR who took patient for thrombectomy and left iliac stent placement on 01/05/2021. Patient tolerated procedure well. Patient was transitioned from heparin drip to Eliquis upon discharge. Patient given vascular follow-up as well as Hematology follow-up.
COVID19 VACCINE	PFIZER\BIONTECH	0951560-1	30-39 years	15-30 days	Severe Right sided chest pain, right sided muscle spasms and difficulty breathing two weeks after vaccine was administered Diagnosis of bilateral pulmonary embolism was made on presentation to ER. No personal or family history of clots in arteries or deep veins or any risk factors in patient. Received heparin drip, pain medications, muscle relaxants inpatient. Pain progressively improved over days. Was discharged after 6 days on admission. Was discharged on oral anticoagulant (Rivaroxaban aka xarelto)
COVID19 VACCINE	PFIZER\BIONTECH	0990853-1	Unknown	15-30 days	Pfizer Covid 19 vaccine treatment under Emergency Use Authorization(EUA): My menstrual cycle has changed and I have started with old brown bleeding with clots 10 days prior to my normal cycle. I have never had this happen and have never had any issues with my periods. Will be seeking medical treatment on 1/27/21 with OBGYN.

COVID19 VACCINE	PFIZER\BIONTECH	1004700-1	65+ years	15-30 days	DVT and probable pulmonary embolus based on hypoxia Patient is physician who cares for patients in NH and ALF where there is documented COVID First dose COVID vaccine 12/20/20, second dose 1/10/20 Some shortness of breath developed about 1/10, not severe 1/30 Leg pain, fever to 101.6 abrupt onset extreme fatigue, ER eval 1.31 negative eval including neg rapid and PCR COVID tests Persistent sx led to repeat ER eval including LE dopper confirming occlusive femoral vein thrombosis; no hypoxia at rest but desat to 85% on exertion (climbing one flight of steps) Started anticoagulants 2/4/21 on home treatment; not working since 1/30/21
COVID19 VACCINE	PFIZER\BIONTECH	1008359-1	40-49 years	15-30 days	I developed acute right posterior pleuritic chest pain and shortness of breath. Diagnosed with multiple pulmonary emboli (see below). I was started on Eliquis initially, but then had worsening symptoms on 2/4/21 and switched to Lovenox injections. Symptoms have been slowly improving since then.
COVID19 VACCINE	PFIZER\BIONTECH	1022516-1	40-49 years	15-30 days	experienced significant shortness of breath, heavy wheezing, and coughing on the weekend of 2/6/2021. Slight wheezing had been ongoing for months (difficulty breathing in January of 2020 when diagnosed with influenza A and intermittent slight wheezing continued throughout the year). Symptoms became worse throughout the weekend. I did continue my normal routine (taking trash to the dump, helped move a heavy tank out of a walkout basement, and moving twelve 40 pound bags of wood pellets from store into truck then from truck into my home on day of hospitalization) Hospitalized on 2/7/2021
COVID19 VACCINE	PFIZER\BIONTECH	1034259-1	65+ years	15-30 days	hospitalized with extensive bilateral pulmonary emboli and right leg deep vein thrombosis after 1st vaccine dose. Required high-flow nasal canula for oxygen support. ultimately discharged on hospice
COVID19 VACCINE	PFIZER\BIONTECH	1035867-1	40-49 years	15-30 days	Noticed swelling in my left hand around Feb 6th, but by Feb 13th entire left arm was swollen and warm and observed blue/purple skin coloring on upper arm and lower arm was red. Went to ER on Feb 15th, and ultrasound revealed a blood clot near the junction of the subclavian vein and cephalic veins. Diagnosis was idiopathic subclavian deep vein thrombosis (DVT). Started on enoxaparin and warfarin on Feb 15th. Referred to hematology and coumadin clinic to monitor INR.
COVID19 VACCINE	PFIZER\BIONTECH	1040552-1	30-39 years	15-30 days	experienced crippling lower abdominal pain followed by very very heavy bleeding and clotting; experienced crippling lower abdominal pain followed by very very heavy bleeding and clotting; experienced crippling lower abdominal pain followed by very very heavy bleeding and clotting; This is a spontaneous report from a contactable healthcare professional (patient). A 32-years-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; batch/lot number and expiration date unknown), via an unspecified route of administration in the left arm on 05Jan2021 10:15 at a single dose for COVID-19 immunization at a hospital. Medical history included idiopathic hypersomnia and allergies to eggplant. The patient has no covid prior to vaccination. Concomitant medications included methylphenidate hydrochloride (CONCERTA), methenamine, levonorgestrel (MIRENA), propranolol hydrochloride (PROPRANOL) and vitamin c [ascorbic acid] (VITAMIN C [ASCORBIC ACID]). The patient had no other vaccine in four weeks. The patient previously took cefazolin and levaquin and experienced allergies to both. The patient has a Mirena IUD and never get her period at all. Within 6 hours of her first Pfizer injection (02Feb2021 16:00), the patient experienced crippling lower abdominal pain followed by very very heavy bleeding and clotting. Resolved within 48 hours as quickly as it came and didn't occur with second dose 1 week out. The patient was not tested for Covid post vaccination. The events were not treated. The outcome of the events was recovered on 04Feb2021. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information and known drug profile it is unlikely that the reported events were causally related to BNT162B2. These are intercurrent conditions. A contributory role of the patient's Mirena IUD should be evaluated. Case will be reassessed if additional information is received. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1047021-1	40-49 years	15-30 days	Patient was admitted s/p hysterectomy, found to have PE and AKI. Patient treated with heparin drip, transitioned to Eliquis and discharged

COVID19 VACCINE	PFIZER\BIONTECH	1052711-1	65+ years	15-30 days	The patient has developed an acute deep venous thrombosis in the right popliteal and trifurcation vessels of the calf. She has an elevated d-dimer of 14,738 and acute hypoxic respiratory failure due to pulmonary embolism.
COVID19 VACCINE	PFIZER\BIONTECH	1053296-1	50-59 years	15-30 days	Left upper extremity DVT and pulmonary embolism diagnosed 2/24/2021. Arm swelling started 02/23/2021.
COVID19 VACCINE	PFIZER\BIONTECH	1069560-1	60-64 years	15-30 days	Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve. VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on

COVID19 VACCINE	PFIZER\BIONTECH	1070750-1	40-49 years	15-30 days	very high Troponin levels (4.79 & 12.49); repeat episodes of chest pain; heart attack; thrombus formation; coagulopathy; myocardial infarction; This is a spontaneous report from a contactable nurse (reporting for herself). A 44-years-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# ELI283), via an unspecified route of administration single dose on 12Jan2021 for covid-19 immunisation. First dose was received on 22Dec2020 10:00 left arm (lot# EJI695). Medical history included chronic skin condition. No other vaccine was received in four weeks. Concomitant medications included oxycodone for pain, colecalciferol (VITAMIN D). The patient experienced myocardial infarction on 10Feb2021 20:00, very high troponin levels (4.79 & 12.49) on 11Feb2021, repeat episodes of chest pain on 10Feb2021 20:00, heart attack on 10Feb2021 20:00, thrombus formation on 10Feb2021 20:00, coagulopathy on 10Feb2021 20:00. The patient was hospitalized due to the events from 11Feb2021. Patient reported to be a healthy 44 year old woman with no history of hypertension or high cholesterol. She was now on 7 different medications to protect her heart, including blood thinners and antihypertensives that result in daily headaches and fatigue. She had had several repeat episodes of chest pain which has required taking sublingual nitroglycerin. She was off work for an undetermined amount of time. Her primary care physician was baffled by her case and reached out to a number of experts who have agreed that her heart attack was caused by a thrombus formation/coagulopathy most definitely related to the Covid vaccines she received. The events outcome was recovered with sequelae.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported event of myocardial infarction and other events. However, the reported events may possibly represent intercurrent medical conditions in this 44-years-old patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including EKG at baseline and during subject drug therapy, echocardiogram, electrolytes, chemistry panel and coronary angiogram, and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1071438-1	65+ years	15-30 days	Patient presented to ED for DVTs, currently being treated with warfarin and heparin bridge. Patient remains in the hospital at this time. Per the EUA, hospitalizations are to be reported irrespective of attribution to the vaccine
COVID19 VACCINE	PFIZER\BIONTECH	1079445-1	65+ years	15-30 days	Unprovoked DVT left lower extremity 2 weeks after second vaccination in a 71 year old, non-obese, non-diabetic with no chronic illnesses who exercises daily and maintains normal weight.
COVID19 VACCINE	PFIZER\BIONTECH	1091908-1	65+ years	15-30 days	DVT blood clot in the right foot, then spread to lower leg and knee and thigh, groin
COVID19 VACCINE	PFIZER\BIONTECH	1092477-1	65+ years	15-30 days	Pericardial effusion; multiple blood clots in portal vein.
COVID19 VACCINE	PFIZER\BIONTECH	1096725-1	30-39 years	15-30 days	4 days after my last vaccine I started getting really intense calf pain like a bad cramp. After the pain just kept getting worse I ended up going to the ER on January 15th 2021. They did an ultrasound and found out I had a dtv. I was also experiencing horrible migraines since the 1st shot I also started seeing black spots in my vision. I also was having fevers and chills
COVID19 VACCINE	PFIZER\BIONTECH	1097807-1	40-49 years	15-30 days	2/27/21 Sudden cardiac arrest due to thrombosis in the LAD
COVID19 VACCINE	PFIZER\BIONTECH	1101806-1	50-59 years	15-30 days	Left femoral DVT
COVID19 VACCINE	PFIZER\BIONTECH	1102909-1	40-49 years	15-30 days	Starting on February 24, 2021, I started to have shortness of breath. This slowly got worse until on March 2, 2021 I was unable to breathe in all the way and was getting a sharp pain in my side/back when I tried to breathe in more than half way. I then went to the emergency room recognizing the symptom as likely being a pulmonary embolism, as I had experienced one four years earlier. It was, in fact, a PE. I was in the hospital for five days as they treated the clots with blood thinners. I slowly got my breathing more back to normal and was discharged. They are still running myriad tests to try to determine the cause or causes, but I thought it wise to report here in case the vaccine is a factor. I received my second dose on 2/26/21, a few days before I went to the hospital but my symptoms started a few days before that.

COVID19 VACCINE	PFIZER\BIONTECH	1104339-1	60-64 years	15-30 days	I am retired handicap-MS. I was doing light housework. I started getting pain in right lung, over course of 2 hours pain became very severe. Only in right lung. Felt like blood clot or pulmonary embolism (which I had 15 yrs ago). Went to hospital, check X-ray no clot/embolisms. Blood work showed no clotting factor. Was admitted 4 days. We treated possibility of MS reaction (solu-methyl) as well as heparin in event of unknown clotting issue. Here?s why this is strange: If this was MS flare/relapse, I would have muscle lockup, drop foot, sight issues, sever balance issues ...(i always have sight issues).. with this even it was only severe lung pain. Did not appear to be MS driven issue. Being educated ?high analytic person, in reflection, My ms is very territorial, it fights anesthesia, colds/flus/covid when my husband had it. My MS gets cranky when my immune system is attacked. I suspect the second covid injection was doing its thing, dna modification, and I had some lung inflammation and my MS compounded the reaction with crippling issue. I was in hospital 4 days, IV fluids, heparin, and steriod IV. Within first 36 hours the extreme lung pain disappeared and I got better. I do have cats scan, mri, X-rays from stay. Cat scan clear, X-ray, normal, mri-classic ms history. Was this Ms event? I?m not sold as I didn?t have other normal MS flare symptoms. Was this injection aggravated? Perhaps... I?m sharing this because I think tracking auto immune disease people is important data gathering. Feel free to call if more dialogue is necessary
COVID19 VACCINE	PFIZER\BIONTECH	1105292-1	65+ years	15-30 days	DVT left calf –> Pulmonary Embolism
COVID19 VACCINE	PFIZER\BIONTECH	1106331-1	65+ years	15-30 days	developed two blood clots in his right calf; pain in his leg; This is a spontaneous report from a contactable consumer reporting for himself. A 70-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number EN9581/expiration date: not provided), via an unspecified route of administration, on 04Feb2021 (at the age of 70 years old) as a single dose for COVID-19 IMMUNIZATION. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE) (lot number EL3249/expiration date: not provided), via an unspecified route of administration, on 15Jan2021 (at the age of 70 years old) as a single dose for COVID-19 IMMUNIZATION. Relevant medical history included was not provided. Concomitant medication included acetylsalicylic acid (BABY ASPIRIN), meloxicam, an allergy medication and anti-depressants. On 19Feb2021, the patient reported that he developed two blood clots in his right calf, one towards his ankle and one towards his knee and pain in his leg which required hospitalization on 22Feb2021. The patient was discharged on the same day, 22Feb2021. Relevant lab data included: blood test on 22Feb2021 were done to determine what medication to put him on. The results of the blood test was unknown. Treatment received for the event thrombosis included abixaban (ELIQUIS) tablets as a blood thinner. The patient reported he never had blood clots in his life. The outcome of the events thrombosis and pain in leg was unknown.
COVID19 VACCINE	PFIZER\BIONTECH	1106925-1	50-59 years	15-30 days	I received my first vaccination on February 11, 2021. On February 17th I was rushed to my local ER with a massive heart attack. I was rushed by helicopter to second hospital where I underwent an emergency Heart Catherization. It was discovered that I will need a triple bypass surgery. However, there is a HUGE blood clot that formed in my heart, and further treatment is on hold for now, until the massive clot has safely dissolved.
COVID19 VACCINE	PFIZER\BIONTECH	1112683-1	65+ years	15-30 days	Extremely tired for the next month, and then was hospitalized with 2 blood clots in lungs and severe anemia (cause not determined yet, as to whether not making platelets or losing blood). Had two blood transfusions and iron transfusion.

COVID19 VACCINE	PFIZER\BIONTECH	1114379-1	50-59 years	15-30 days	I was transported by ambulance and admitted to the hospital with numerous blood clots in my lungs after I could not breathe.; I was transported by ambulance and admitted to the hospital with numerous blood clots in my lungs after I could not breathe.; This is a spontaneous report from a contactable consumer (patient). A 51-year-old female patient (not pregnant) received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9265) on 30Jan2021 09:00 (age at vaccination was 50-year-old) on left arm for COVID-19 immunisation. Medical history included hypothyroidism. No Known allergies. Concomitant medications in two weeks included thyroid (ARMOUR THYROID), ethinylestradiol, levonorgestrel (SEASONALE) and cetirizine hydrochloride (ZYRTEC). No other vaccine in four weeks. The patient previously took first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3246) on 07Jan2021 14: 15 (age at vaccination was 50-year-old) on left arm for covid-19 immunization. Facility type vaccine was Hospital. She was transported by ambulance and admitted to the hospital with numerous blood clots in her lungs after she could not breathe on 22Feb2021 09:45 AM. AE resulted in Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event). Treatment received as Angioplasty to remove bigger clots. No covid prior vaccination. Nasal Swab test (PCR) on 22Feb2021 was negative. The outcome of the events was recovering.
COVID19 VACCINE	PFIZER\BIONTECH	1119104-1	65+ years	15-30 days	Non-productive cough, shortness of breath, increase in blood pressure (170/90) and increased heart rate (85 bpm). Symptoms began shortly after second dose of vaccine on 2/26/2021
COVID19 VACCINE	PFIZER\BIONTECH	1121617-1	65+ years	15-30 days	Plantar thrombosis - several SVT &DVT in multiple veins & artery of left foot.; several SVT &DVT in multiple veins & artery of left foot; several SVT &DVT in multiple veins & artery of left foot; Pain & swelling of foot; Pain & swelling of foot; This is a spontaneous report from a contactable consumer. This consumer (patient) reported that a 74-years-old female patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration, administered in Arm Left on 12Feb2021 12:00 AM (Batch/Lot Number: EM9810) as SINGLE DOSE for covid-19 immunisation. Medical history included known allergies: Some antibiotics cause autoimmune issues, all sulphate drugs, narcotics. Historical vaccine included first dose of Pfizer COVID 19 vaccine (lot_number=EL3249) on 22Jan2021 12:00 AM administered in Right arm. Concomitant medications included thyroid (NATURE THROID) and multiple vitamin, taken for an unspecified indication, start and stop date were not reported. The patient experienced Plantar thrombosis - several SVT &DVT in multiple veins & artery of left foot. Pain & swelling of foot, all on 06Mar2021 01:00 AM with outcome of not recovered. Events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Life threatening illness (immediate risk of death from the event). Treatment received for events included given Eliquis to avoid further clotting. No other vaccine in four weeks. No covid prior vaccination. No covid tested post vaccination.
COVID19 VACCINE	PFIZER\BIONTECH	1131656-1	50-59 years	15-30 days	Day of shot developed pain in entire right side(chest area), also acid reflux and nausea. That went away about 12 hours after the vaccine. Ten days after I developed a slight pain in right lateral side that progresses to constant pain in 2 places on right side including under right clavicle. I had pain upon taking in a deep breath. Saw MD after 4 days of these SXS. Performed labs, Chest x-ray and EKG. All were essentially normal except elevated WBC count. Have 2 COVID test which were both normal. Md said possibly some sort of inflammation and suggested taking anti-inflammatories which did not help much at all with SXS. After a few more days the SXS changed to constant chest pain(pressure), SOB upon exertion and pain behind knee. F/U with MD again and it was decided to wait a few more days. Upon suggestion from friend asked MD to perform D-Dimer lab test. The result was 4,400. My normal value should have been 550. Sent to ER. CT of chest, EKG and more labs performed. CT revealed large bilateral pulmonary embolisms in pulmonary arteries. Started on blood thinners. Ultrasound of left leg revealed large DVT. Sent home after 2 days on blood thinners. SXS stopped after a few days.

COVID19 VACCINE	PFIZER\BIONTECH	1135581-1	65+ years	15-30 days	multiple bilateral DVTs; pulmonary embolus; This is a spontaneous report from a contactable Physician (Patient). A 66-year-old male patient received second dose of bnt162b2 (BNT162B2, Solution for injection, Lot number: EN6200, Expiration date was not reported), via an unspecified route of administration, in Arm Left on 23Feb2021 13:15 as single dose, the first dose via an unspecified route of administration, a in Arm Left on 02Feb2021 13:15 as single dose for covid-19 immunization. Medical history included Subarachnoid hemorrhage (SAH), hypertension (htn), degenerative discs, malignant melanoma and prostatectomy (2 years 3 months). Concomitant medications included atorvastatin calcium and lisinopril taken for an unspecified indication, start and stop date were not reported. The patient previously took cephalosporin for allergies. After receiving the second dose patient experienced pulmonary embolus on an unspecified date in 2021 and multiple bilateral DVTs diagnosed on 11Mar2021. As per the reporter seriousness criteria reported as emergency room/department or urgent care, Life threatening illness (immediate risk of death from the event). Patient did not receive any other vaccine in four weeks. Patient did not have Covid prior vaccination. Patient was not tested Covid post vaccination. Therapeutic measures were taken as a result of pulmonary embolus multiple bilateral dvt. The outcome of the events was not recovered.; Sender's Comments: Based on the temporal relationship, A possible contributory role of the suspect product to the development of Pulmonary Embolus and Deep Vein Thrombosis cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1138541-1	65+ years	15-30 days	Principal Final Diagnosis: Acute saddle pulmonary embolism with acute cor pulmonale (HCC) Secondary Diagnoses: Active Hospital Problems Diagnosis Date Noted ? Acute saddle pulmonary embolism with acute cor pulmonale (HCC) 02/09/2021 ? Acute thrombus of right ventricle (HCC) 02/09/2021 ? Right-sided epistaxis 02/09/2021 ? Melena 02/09/2021 ? Essential hypertension 02/28/2020
COVID19 VACCINE	PFIZER\BIONTECH	1144648-1	65+ years	15-30 days	Pulmonary embolism (CMS/HCC) COVID-19
COVID19 VACCINE	PFIZER\BIONTECH	1145963-1	65+ years	15-30 days	bilateral pulmonary emboli; ER ultrasound of legs (no clots); CT scan showed PEs; administered 2 shots Lovenox; Rx 10 mg Eliquis 2x/day for 1 week, then 5 mg 2x/day.
COVID19 VACCINE	PFIZER\BIONTECH	1146684-1	50-59 years	15-30 days	Pt received second dose of COVID vaccine at hospital on 2/19 (date given by pt). Pt had been more sedentary than usual due to winter season. As weather warmed and pt became more active, she began to experience symptoms of left lower extremity DVT on 3/15. Pt evaluated at urgent care on 3/19 and was sent to medical center for follow up. Lower extremity dopplers were negative for DVT. Pt presented to orthopedic surgeon for follow up because symptoms not resolved and was placed on Medrol Dosepak for possible issues related to remote hip replacement. When symptoms progressed, pt presented to hospital on 3/24. 3/24 lower extremity dopplers revealed thrombus in left leg that extended into saphenofemoral junction. Patient was then transferred to hospital for L iliac venous EKOS catheter placement for catheter-directed thrombolysis with alteplase on 3/25. Pt underwent second procedure on 3/26 where Angiojet thrombectomy and venoplasty of left external iliac, common femoral and femoral vein was performed.

COVID19 VACCINE	PFIZER\BIONTECH	1146761-1	65+ years	15-30 days	<p>""widow maker"" type heart attack where the LAD artery suddenly became 100% blocked by a blood clot;  ""widow maker"" type heart attack where the LAD artery suddenly became 100% blocked by a blood clot;  ""widow maker"" type heart attack where the LAD artery suddenly became 100% blocked by a blood clot;  Cardiogenic shock; Anterior myocardial infarction; This is a spontaneous report from a contactable consumer. An 81-years-old female patient received BNT162B2, dose 2 via an unspecified route of administration, administered in left arm on 06Feb2021 (Batch/Lot number was not reported) as single dose for COVID-19 immunisation. Medical history included very sensitive to medication effects (usually takes only 1/2 dose with strong efficacy to avoid side effects). Breast cancer survivor (2014 onset, 2019 declared permanent remission) and mild blood pressure treated successfully with medication for about 10 years. Concomitant medications included spironolactone and valsartan, both taken for blood pressure. The patient previously received first dose of BNT162B2 on 16Jan2021 in left arm for COVID-19 immunization. The reporter's mother died 3 weeks and 6 days after having received the second dose of the Pfizer covid vaccine. The cause of death was a ""widow maker"" type heart attack where the LAD artery suddenly became 100% blocked by a blood clot; the event began about 11:45pm on 04Mar2021. The blockage was confirmed via cardiac cath procedure performed within 2 hours of the onset by Doctor, he removed the clot and placed a stent. However her heart was too damaged and could not recover. Doctor confirmed to us that she did not have excessive or evidence of any prior blockage and not excessive plaque. The blood clot likely came on and caused the cardiac event within roughly an hour, he explained. The patient had no prior symptoms and no comorbidities for blood clotting and was full of life and energy on 05Mar up to when she went to bed that night. She died 06Mar at 4:04 am at hospital. The strat date of the events was reported as 04Mar2021 at 11:45 PM. AE resulted in emergency room/department or urgent care, life threatening illness (immediate risk of death from the event). The patient died on 06Mar2021. An autopsy was not performed. The death cause: Triggered by the sudden 100% blockage of the LAD by a blood clot, the cause of death is listed as (A) Cardiogenic shock (B) Anterior myocardial infarction. Treatment was received for the events which included multiple resuscitations and angioplasty surgery. No covid prior vaccination, no covid tested post vaccination. The outcome of the events was fatal. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: ""widow maker"" type heart attack where the LAD artery suddenly became 100% blocked by a blood clot; ""widow maker"" type heart attack where the LAD artery suddenly became 100% blocked by a blood clot; ""widow maker"" type heart attack where the LAD artery""</p>
COVID19 VACCINE	PFIZER\BIONTECH	1148105-1	65+ years	15-30 days	BLOOD CLOTS : Two days after receiving Pfizer dose 2 my mother had difficulty breathing and had chest pain. She was hospitalized for six days due to blood-clotting in the lungs.
COVID19 VACCINE	PFIZER\BIONTECH	1150166-1	65+ years	15-30 days	Stroke (blood clot in right brain), resulting in slurred speech and left-side weakness

COVID19 VACCINE	PFIZER\BIONTECH	1154148-1	50-59 years	15-30 days	DVT (deep vein thrombosis) in right medial subclavian; superficial thrombosis in right proximal basilic vein; right arm swelling in the setting of receiving her Pfizer covid vaccine in the right arm 1 week prior; This is a spontaneous report received from a contactable healthcare professional. A 51-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 intramuscular, administered in arm right in Mar2021 (Batch/Lot number was not reported) as a single dose for COVID-19 immunization. Medical history included hyperlipidemia, acute pancreatitis, May-Thurner syndrome, and allergies: penicillin, IV contrast. Concomitant medications included drospirenone, ethinylestradiol betadex clathrate (YAZ), fenofibrate, and levothyroxine. Patient is not pregnant at the time of vaccination. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. Patient has not been tested for COVID-19 since the vaccination. Patient was seen at the ED for right arm swelling in the setting of receiving her Pfizer COVID vaccine in the right arm 1 week prior. She was found to have a DVT (deep vein thrombosis) in right medial subclavian and superficial thrombosis in right proximal basilic vein. The events started on 17Mar2021 09:00. AE resulted in emergency room/department or urgent care. Patient was recovering from the events. Treatment for AEs include anticoagulation. Information about lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of subject vaccine cannot be excluded for the DVT and other reported events, based on temporal relationship. However the reported events may likely represent intercurrent medical conditions in this patient. There is very limited information provided in this report. This case will be reassessed upon receipt of follow-up information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1154679-1	40-49 years	15-30 days	Patient reports he has noticed over the past week increased shortness of breath on exertion—at baseline able to exercise with walking 45-60 minutes without dyspnea, however noticed over the last week getting some shortness of breath even walking to the garage. No chest pain, no fevers, chills, cough. He saw his PCP for these symptoms who ordered EKG and CXR 1 day PTA which per patient were normal—plan was for referral to cardiologist. However on the morning on presentation around 6:45 AM after taking an elevator for work he began feeling lightheaded and lost consciousness, awakening on the floor. He went home as he was not feeling well however proceeded to have another 2-3 episodes of loss of consciousness at home witnessed by his girlfriend—the later 2 occurred while lying down and were not clearly associated with any presyncopal symptoms.
COVID19 VACCINE	PFIZER\BIONTECH	1156669-1	65+ years	15-30 days	bilateral pulmonary embolism

COVID19 VACCINE	PFIZER\BIONTECH	1158680-1	40-49 years	15-30 days	documented MRI stroke; Appears to be thromboembolic; This is a spontaneous report from a contactable physician (reported for himself). A 48-years-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Solution for injection, lot number and expiry date were not reported), via an unspecified route of administration, administered in right arm on 04Jan2021 07:00 as a single dose for COVID-19 immunisation. Medical history included allergies to penicillin. The patient's concomitant medications were not reported. The patient had no other vaccine in four weeks. The patient had no covid prior vaccination. On 27Jan2021 14:00, it was reported that patient had documented MRI stroke, and appeared to be thromboembolic. Patient have no risk factors for CVA, and stroke occurred. The patient underwent lab tests and procedures which included MRI (magnetic resonance imaging): stroke on 27Jan2021. Events resulted in doctor or other healthcare professional office/clinic visit, emergency visit and disability or permanent damage. Therapeutic measures were taken in response to the events which included patient had started on aspirin. The patient was not tested for covid post vaccination. The outcome of the events stroke and thromboembolic was recovering. Information about lot/batch number is requested.; Sender's Comments: The causal association cannot be excluded between the reported events of ""MRI stroke and appeared to be thromboembolic"" and BNT162B2 use. The impact of this report on the benefit-risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for AE. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, ethics committees and investigators, as appropriate.""
COVID19 VACCINE	PFIZER\BIONTECH	1162068-1	65+ years	15-30 days	Swelling of vocal chords followed by need to blow nose which caused bleeding and clotting in nostrils.; Swelling of vocal chords followed by need to blow nose; Swelling of vocal chords followed by need to blow nose which caused bleeding and clotting in nostrils.; Causes constant congestion.; crusted scabs from nose for over two week timeframe.; This is a spontaneous report from a contactable consumer (patient). An 81-year-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number; EL9264), via an unspecified route of administration administered in left arm on 09Feb2021 as SINGLE DOSE for COVID-19 immunisation. The patient was not pregnant at the time of vaccination. The patient had no COVID prior to vaccination. Medical history included osteoarthritis, osteoporosis, neuropathy, hypothyroidism, thyroidectomy, hysterectomy, and two recent falls. The patient had no known allergies. Concomitant medication included influenza vaccine (FLU) taken for immunisation. Historical vaccine includes first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: EL3249) on 19Jan2021 at 04:30 PM administered in the right arm for COVID-19 immunization. The patient experienced swelling of vocal chords followed by need to blow nose which caused bleeding and clotting in nostrils. The patient was constantly blowing up bloody clots/crusted scabs from nose for over two week timeframe. At first, was a lot of clots, red blood and scabs. It got better over 14 days, but, still persists. Now clots and scabs are smaller but still frequent. Causes constant congestion. All events started on 05Mar2021 at 12:00 AM. The events resulted in doctor or healthcare professional visit/clinic visit. There was no treatment received for all events. The patient was COVID tested (nasal swab) post vaccination on 09Mar2021 which was negative. The patient had not yet recovered from all events.
COVID19 VACCINE	PFIZER\BIONTECH	1163548-1	40-49 years	15-30 days	10 days after my first shot my feet were swollen and I didn't feel well by 18 days after it was not getting better. I got my 2nd shot on day 21 and the day after I got an alert on my Watch regarding resting heart rate exceeding 125bpm and have been inactive for 10mins, so my husband call the doctor's office to make an appointment. They said we could go to the appointment or hospital, so we went to the hospital.
COVID19 VACCINE	PFIZER\BIONTECH	1168104-1	30-39 years	15-30 days	Pfizer COVID Vaccine treatment under Emergency Use Authorization(EUA): Vaccination received 3/2/2021. On 3/16/2021, maternal cardiac arrest, terminal fetal bradycardia, emergent C-section. Likely amniotic fluid embolism and DIC.
COVID19 VACCINE	PFIZER\BIONTECH	1168135-1	65+ years	15-30 days	Pt developed intermittent shortness of breath around 3/7/21. Pt fell and had left arm and leg weakness. Pt had transient ischemic attack, multiple pulmonary emboli and deep venous thrombosis diagnosis on 3/27/21
COVID19 VACCINE	PFIZER\BIONTECH	1170538-1	65+ years	15-30 days	pt developed saddle pulmonary embolus

COVID19 VACCINE	PFIZER\BIONTECH	1175179-1	65+ years	15-30 days	This is a spontaneous report from a contactable consumer. A 73-year-old male patient received his second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN9581), via an unspecified route of administration in left arm on 10Feb2021 (Batch/Lot Number: EN9581) as a single dose for COVID-19 immunisation. Medical history included hypertension, prolactinoma, hyper cholesterol, and allergies to penicillin. Concomitant medications received within 2 weeks of vaccination included verapamil, lisinopril, atorvastatin, and omeprazole. The patient previously received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3248) in the left arm on 20Jan2021 01:00 PM. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. He was not diagnosed with COVID-19 prior to vaccination. The patient experienced stroke due to blood clot at superior sagittal sinus of brain on 11Mar2021 13:00. The events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, and Hospitalization for 6 days. Treatment received for the adverse event included Enoxaparin injections and warfarin. Outcome of events was not recovered. The patient had not been tested for COVID-19 since the vaccination.
COVID19 VACCINE	PFIZER\BIONTECH	1177687-1	65+ years	15-30 days	symptoms, signs, time course, etc.) 78 yo female patient with PMHx of paroxysmal atrial fib / COPD / smoking / anxiety-depression / obesity / arthritis and prior bil PE in 2018 after knee surgery (anticoagulated with Xarelto) who presented to FH on 03/30/2021 with SOB x2 weeks. Of note she received her 2nd COVID vaccine dose on 03/05/2021 and since she has worsening SOB. Pt reported cough w/ yellow sputum prior to her admission. At urgent care, she was hypoxic with Sat 82%, therefore she was transferred to ED for further w/u. Lab w/u showed BNP of 1,074 and trop of 32. She was found to have a negative POC COVID-19 and PCR is pending. Bil venous Dopplers show acute occlusive DVT in the R popliteal vein above and below the knee w/ slow flow in the R fem vein and no DV IN the LLE. TTE on 03/31/2021 showed EF 65-70% w/ G2DD, mod-severe RV failure and severe pulmonary HTN, mod TR, and dilated IVC. Decision was made to CT chest w/ contrast despite renal function given high suspicion for PE. CT chest w/ contrast showed large clot burden PE w/ findings c/w R heart strain, a 12x9 mm lobulated nodule in the RUL concerning for neoplasm, increasing patchy infiltrates, and increasing R pleural effusion and new trace L pleural effusion. Patient required 12L O2 via NC. IR was contacted at but felt that patient was not a candidate for CDT or for IVC filter. Patient was transferred to ICU for further care. Patient received IV heparin per the PE Protocol from, Alteplase 40mg on 4/1, and was started on treatment dose of Eliquis.
COVID19 VACCINE	PFIZER\BIONTECH	1179718-1	60-64 years	15-30 days	Two weeks after receiving the vaccine I went to the ER with excruciating pain in my chest. Was diagnosed with a pulmonary embolism. My son who is 33 yes old had the same result after his first Pfizer vaccine in the exact same time frame - yesterday.
COVID19 VACCINE	PFIZER\BIONTECH	1181590-1	65+ years	15-30 days	Sob started 3/18/2021 Admitted with dvt and pe 4/7/2021
COVID19 VACCINE	PFIZER\BIONTECH	1182181-1	65+ years	15-30 days	Patient presented to ER with R back pain paresthesia. CTA performed:Segmental and subsegmental pulmonary emboli involving the left upper lobe.
COVID19 VACCINE	PFIZER\BIONTECH	1182773-1	50-59 years	15-30 days	Massive blood clot in left calf leading to pulmonary embolisms in both lungs (multiple clots in each lung); Massive blood clot in left calf leading to pulmonary embolisms in both lungs (multiple clots in each lung); This is a spontaneous report from a contactable consumer (patient). A 58-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration administered in left arm on 21Feb2021 14:00 (at the age of 58-year-old) as SINGLE DOSE for COVID-19 immunisation. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination and it was unknown if the patient has been tested for COVID-19 since the vaccination. The patient's medical history was not reported. The patient had no allergies to medications, food, or other products. The patient had no concomitant medications received within 2 weeks of vaccination. On 10Mar2021 at 11:30 AM, the patient experienced massive blood clot in left calf leading to pulmonary embolisms in both lungs (multiple clots in each lung). The patient was hospitalized for the events for 4 days. The events were also considered as life-threatening. Therapeutic measures were taken as a result of massive blood clot in left calf leading to pulmonary embolisms in both lungs (multiple clots in each lung) which included intravenous anticoagulants and injected anticoagulant. The patient was recovering from the events. Information about the lot/batch number has been requested.

COVID19 VACCINE	PFIZER\BIONTECH	1182831-1	65+ years	15-30 days	multiple PE and DVT, admitted 3/5/21 on heparin and then eliquis
COVID19 VACCINE	PFIZER\BIONTECH	1188012-1	40-49 years	15-30 days	I was diagnosed with a pulmonary embolism on 1/15/21
COVID19 VACCINE	PFIZER\BIONTECH	1189666-1	40-49 years	15-30 days	Pulmonary Embolism. Emergency open heart surgery. Coded for 4 minutes. In ICU and Hospital. Kidney failure.....Total blockage of left lung. 9 inch clot in right ventricle.
COVID19 VACCINE	PFIZER\BIONTECH	1191609-1	40-49 years	15-30 days	Approximately one week after my second dose my right leg began swelling. For three weeks after the swelling began it would get better than get worse. On Tuesday, March 30, 2021 my entire leg swelled to twice its normal size at which time I went to the emergency room and a blood clot was diagnosed in my right leg. I completed a multitude of tests and bloodwork with a hematologist and there are no factors or reasons they can identify as to why I developed a blood clot.
COVID19 VACCINE	PFIZER\BIONTECH	1191881-1	65+ years	15-30 days	Hospitalized with blood clots in his lungs and a-fib; Hospitalized with blood clots in his lungs and a-fib; This is a spontaneous report from a contactable consumer. A 74-year-old male patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Left on 01Mar2021 (Batch/Lot number was not reported) as single dose for COVID-19 immunization. Medical history included covid-19 prior vaccination: Yes. The patient had no known allergies. The patient's concomitant medications were not reported. The patient previously took bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) for COVID-19 immunization. On 22Mar2021 at 10:00 (reported as 3 weeks after the his second shot), the patient was hospitalized with blood clots in his lungs and a-fib. The patient was currently in the hospital. The patient was treated with oxygen and anticoagulant. The outcome of the events was not recovered. Follow-up attempts are completed. No further information is expected.
COVID19 VACCINE	PFIZER\BIONTECH	1199422-1	65+ years	15-30 days	Patient passed away from blood clot, did not feel well after 2nd shot
COVID19 VACCINE	PFIZER\BIONTECH	1200617-1	65+ years	15-30 days	Developed a fever and diagnosed with pulmonary embolus
COVID19 VACCINE	PFIZER\BIONTECH	1200939-1	40-49 years	15-30 days	Massive PE, patient died. No history of DVT, we did a COVID test here and it was negative. She had no PMH, we suspect the vaccine made her hypercoagulable. Had pleuritic CP, tachycardia, tachypnea.
COVID19 VACCINE	PFIZER\BIONTECH	1201408-1	65+ years	15-30 days	Severe drop in platelets and blood clots.
COVID19 VACCINE	PFIZER\BIONTECH	1202374-1	65+ years	15-30 days	Acute pulmonary embolus with mild right heart strain. Woke at 3am on 4-3-21 with severe pain and difficulty breathing, went to emergency room and was given a CT scan, diagnosed and treated with Heparin IV. drip and admitted to the hospital. Later an ultrasound test showed another clot in my left leg so I was started on Apixaban (Eliquis) 5 milligram . Released and sent home on 4-5-21
COVID19 VACCINE	PFIZER\BIONTECH	1203152-1	65+ years	15-30 days	Started experiencing wheezing and shortness of breath and reduction of oxygen level below 90 prior to entering the ER on Sunday, March 21, 2021. Noticed particular shortness of breath Saturday before entering ER. Oxygen levels ran between 92 and as low as 87 that Saturday afternoon and Sunday morning. Also had severe stomach pain which was determined to be caused by gall bladder stone.
COVID19 VACCINE	PFIZER\BIONTECH	1204579-1	65+ years	15-30 days	Jan 13 first dose received...Jan 30th collapsed at night by herself. Was able to get up and go back to bed. Next day was taken to urgent care and sent by emergency to hospital. Suffered large blood clot in the leg that broke off and traveled to the lungs. Acute saddle pulmonary embolism with acute cor pulmonale. Was put on blood thinners and released from hospital on 2/2. As soon as we got home from the hospital she suffered from a massive gastrointestinal intestinal bleed and had to be rushed back to the hospital. Two days later while still in the hospital she suffered a mild heart attack and had a stent inserted.
COVID19 VACCINE	PFIZER\BIONTECH	1205103-1	65+ years	15-30 days	On February 20, 2021 in the early evening my husband began to experience chest pain and pressure, took Tylenol, however did not relay the symptoms to me. About 6:50 AM on February 21, 2021 told me that he did not feel well, had chest pain and pressure in his chest. An ambulance was called and my husband was transported to the Hospital. I was contacted by the treating physician and was told that my husband suffered with a Pulmonary Embolism (sp?). He was started on Heparin and admitted to the hospital. Later that evening his medication was changed to Eliquis. He was released from hospital the following evening. He has since followed up with his primary care.

COVID19 VACCINE	PFIZER\BIONTECH	1205143-1	Unknown	15-30 days	DVT; blood in urine; This is a spontaneous report from a contactable consumer (patient) via the Pfizer-sponsored program. A patient of unspecified age and gender received the second dose of bnt162b2 (BNT162B2, Solution for injection lot number and expiry date were not reported), via an unspecified route of administration on 25Feb2021 as single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient previously received the first dose of bnt162b2 (BNT162B2, Solution for injection lot number and expiry date were not reported), on 03Feb2021 for COVID-19 immunization. On 24Mar2021, the patient had blood in urine. After visiting ER (emergency room) 2 times, the patient got DVT (Deep Vein Thrombosis). The doctors were also not sure if that's because of the shot or not. Outcome of the events was unknown. Information on the lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1205227-1	Unknown	15-30 days	I got DVT-Deep Vein Thrombosis; blood in my urine; This is a spontaneous report from a contactable consumer (patient) via the Pfizer sponsored program. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration on 25Feb2021 (Batch/Lot number was not reported) as a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. Historical vaccine included PFIZER BIONTECH COVID 19 VACCINE first dose on 03Feb2021 for COVID-19 immunisation. The patient got dvt-deep vein thrombosis on an unspecified date with outcome of unknown and blood in urine on 24Mar2021 with outcome of unknown. It was mentioned that the patient got first shot on 03Feb21, and second shot on 25Feb21. But on 24Mar21, blood in his/her urine. After visit ER 2 times, the patient got DVT (Deep Vein Thrombosis). Also doctors were not sure that's because of the shot or not. Information on the lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1205989-1	65+ years	15-30 days	Blood clots in leg and both lungs; shortness of breath. Shortness of breath for 1 week before seeking medical attention on March 7th. Admitted to hospital through emergency room on March 8th. Hospitalized from March 8-14. Put on Coumadin. Sent home with supplemental oxygen.
COVID19 VACCINE	PFIZER\BIONTECH	1206307-1	40-49 years	15-30 days	I was admitted to ER with stroke and right arm weakness. While I was in the ER, I also developed unconsciously seizure. The diagnosis are Cerebral Venous Thrombosis (CVT, multiple clots) and Cerebral Venous Sinus Thrombosis (CVST), Focal motor seizure and Cerebral Edema.
COVID19 VACCINE	PFIZER\BIONTECH	1207571-1	65+ years	15-30 days	er visit turned into a hospital stay in ICU....due to blood clots that were in the lungs that were so pervasive a heart attack ensued due to the pressure from the lungs
COVID19 VACCINE	PFIZER\BIONTECH	1208225-1	65+ years	15-30 days	Weakness in left leg, blod clots in lungs, severe headaches continuing I went to emergency on February 23, 2021 where I treated for weakness in left leg and was admitted to hospital where I received treatments for a double pulmonary embolism on March 1.
COVID19 VACCINE	PFIZER\BIONTECH	1209596-1	60-64 years	15-30 days	4-1-21-headache, indigestion, 4-2-21 ER visit, with admission, R/O MI. 4-3-21 transferred via ambulance for pulmonary embolism almost occluding pulmonary artery with peripheral and additional pulmonary clots. Performed thrombectomy immediately on arrival to hospital. Then 48 hours heparin therapy, home on Eliquis
COVID19 VACCINE	PFIZER\BIONTECH	1210894-1	40-49 years	15-30 days	Blood clot in lower right leg (calf), resulting in pulmonary embolisms and use of blood thinners. Due to fibroids, this caused excessive bleeding leading to anemic condition and the need for several blood and iron transfusions. Solution was to perform hysterectomy to eliminate fibroids and bleeding to be able to continue use of blood thinners for blood clot condition.
COVID19 VACCINE	PFIZER\BIONTECH	1211255-1	65+ years	15-30 days	Leg swelling, DVT, P.E., shortness of breath
COVID19 VACCINE	PFIZER\BIONTECH	1211330-1	40-49 years	15-30 days	Patient was seen at Hospital for seizure, fall and head injury. Subsequent workup following transfer to another hospital revealed L frontal lobe parenchymal hematoma with overlying subarachnoid hemorrhage, no underlying aneurysm or vascular malformation. He had MRI with and without contrast revealing partial occlusion and thrombus of the superior sagittal sinus with adjacent hemorrhage and edema. Treated with heparin, transitioned to coumadin.
COVID19 VACCINE	PFIZER\BIONTECH	1213431-1	40-49 years	15-30 days	Patient admitted with massive portal vein thrombosis and low plt in setting of infection. Symptoms started one week prior
COVID19 VACCINE	PFIZER\BIONTECH	1214418-1	65+ years	15-30 days	bilateral multiple pulmonary emboli (left and right main pulmonary arteries)

COVID19 VACCINE	PFIZER\BIONTECH	1214456-1	65+ years	15-30 days	Critical Limb Ischemia Symptoms: Progressive BL lower extremity and back pain starting on 3/20/2021. She presented to the ED twice and DVT ultrasound and lumbar spine CT showed no acute findings. Symptoms progressed to the point of severe pain on 4/1/2021 with toe numbness and paralysis. CTA of BL lower extremities was performed showing bilateral arterial thrombus. She underwent bilateral common femoral artery thromboembolotomy with vascular surgery. Of note, patient was on eliquis 5 mg BID given history of PE in 2018. She was compliant with this medication.
COVID19 VACCINE	PFIZER\BIONTECH	1214605-1	40-49 years	15-30 days	Bilateral pulmonary embolism which was diagnosed on 4/14/21 after 2 days of severe shortness of breath. Associated with hypoxia requiring supplemental oxygen. Patient is morbidly obese which is only other risk factor for pulmonary embolism. He denies history of increased sedentary activity, denies recent travel, denies known history of a hypercoagulable disorder or family history of blood clots. No other causative factors for the pulmonary emboli have been identified.
COVID19 VACCINE	PFIZER\BIONTECH	1214969-1	65+ years	15-30 days	Found to have bilateral pulmonary emboli on CT scan done April 5, 2021. He was asymptomatic. Was a scheduled CT to follow-up on previous pulmonary nodules and the PE's were seen. No other reason for the PE's has been found at this time.
COVID19 VACCINE	PFIZER\BIONTECH	1215826-1	65+ years	15-30 days	I26.99 - Pulmonary emboli (CMS/HCC) J18.9 - Atypical pneumonia N17.9 - Acute kidney injury (CMS/HCC) R73.9 - Hyperglycemia A41.9 - Sepsis (CMS/HCC)
COVID19 VACCINE	PFIZER\BIONTECH	1219245-1	65+ years	15-30 days	Pulmonary embolism
COVID19 VACCINE	PFIZER\BIONTECH	1219410-1	50-59 years	15-30 days	03/06//2021: Seen in ER for severe headache. BP checked and was good. Covid test = Neg. Labs drawn and shows low plt count. MRI showed lesions/clots on brain. test for Lupus = Neg. Hep panel = Neg. Admitted to hospital for 17 days. Treatment with plasmapheresis, rituximab and steroids.
COVID19 VACCINE	PFIZER\BIONTECH	1224177-1	18-29 years	15-30 days	Blood clot blocking blood flow to brain - 1st episode: ( 3/12/21) stabilized, minor limited movement left side - 2nd episode: (3/24/21) no blood flow to brain, death (maintained on life support for organ donation)
COVID19 VACCINE	PFIZER\BIONTECH	1224391-1	50-59 years	15-30 days	small peripheral right lower lobe pulmonary embolism; anaphylaxis; whole body rash and erythema; whole body rash and erythema; This is a spontaneous report received from a contactable physician. A 57-year-old male patient received BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration on 01Mar2021 (at the age of 57-year-old) as single dose for COVID-19 immunization. Medical history included joint pain and ongoing 45-packs per year smoker. The patient did not have any allergies to medications, food, or other products. Concomitant medications included salbutamol (ALBUTEROL), hydroxyzine (manufacturer unknown) and diclofenac sodium (manufacturer unknown). The patient did not receive any other vaccines within four weeks prior to the vaccination. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The physician reported, ""patient had anaphylaxis and whole-body rash and erythema on separate hospitalization (I was not involved for this but reviewed photos and this was reportedly attributed to the vaccine; I'm uncertain if that event was reported). On hospitalization, the patient was with small peripheral right lower lobe pulmonary embolism on a CT PE (CT scan for Pulmonary Embolus). Patient is an active smoker. No other obvious cause."" As a result of the adverse events (unspecified), the patient was hospitalized for one day. The start date of the events was on 29Mar2021. The patient was treated with apixaban (for pulmonary embolism). The clinical outcome of ""anaphylaxis and whole-body rash and erythema"" and ""small peripheral right lower lobe pulmonary embolism"" was resolving. The lot number for the vaccine, BNT162b2, was not provided and will be requested during follow-up.; Sender's Comments: Based on temporal association, a possible contributory role of BNT162B2 cannot be excluded for events pulmonary embolism, anaphylactic reaction and associated generalized rash and generalized erythema. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.""

COVID19 VACCINE	PFIZER\BIONTECH	1224548-1	65+ years	15-30 days	<p>found down unconscious; unwitnessed fall; oxygen was in the 60s; submassive bilateral pulmonary emboli; right femoral vein emboli/ occlusive thrombus visualized in the right proximal femoral vein; some degree of right heart dysfunction; blood sugar very high; A1C elevated; Haptoglobin elevated; elevated troponin; This is a spontaneous report from a contactable nurse. A 67-year-old male patient received second dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; Lot number was not reported) via an unspecified route of administration, at the age of 67-year-old, on 25Feb2021, as SINGLE DOSE for covid-19 immunisation. Medical history included Traumatic brain injury at the age of 29 which resulted in a CVA (right sided stroke)because the hospital did not know how to give Mannitol, behavioral problems in 2008, run over by a train in 2008, wears two AFOs (one on the left leg from having a right sided stroke, he also wears one on his left leg from having a stroke with right sided weakness, the right AFO was worn since he was 29, and then the other one he started wearing in 2008 when he was run over by a train and almost had his leg severed and he wears a left AFO), dementia diagnosed 4-5 years ago, head surgeries, depression, affective disorder, anxiety. The patient had multiple hospitalizations, and he has hyper reflexivity like all brain patients have. The patient has no history of blood clots or emboli. Concomitant medications included olanzapine (ZYPREXA) taken for depression and oxcarbazepine (TRILEPTAL) taken for affective disorder and anxiety. The patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number not reported) single dose for covid-19 immunisation, pneumonia and flu vaccine in 2008 for immunization and has no reaction. The patient received his second dose of the vaccine on 25Feb2021 and two weeks later he was found down/ was found down unconscious at the nursing home and his oxygen was in the 60's on 15Mar2021. The nursing home did not know if her brother hit his head because it was unwitnessed. The patient was found down, not responsive, and it was an unwitnessed fall. The patient was treated as a trauma patient and that this occurred around 10 o'clock on 15Mar2021. At that time, he was transferred to a local hospital to the emergency room and put on oxygen. They transferred him within 4 hours because they did not know what to do. Caller adds that the hospital thought that he had a subdural hematoma but the hospital does not have a neuro radiologist, so the hospital transferred to the other hospital that somebody with head knowledge can look at his CAT scan. The patient was misdiagnosed with a subdural hematoma because there were changes in his CT scan from his 3 previous brain surgeries. The patient had a traumatic brain injury when he was 29, and experienced changes. The patient was found to have submassive bilateral pulmonary emboli on 15Mar2021 described as central lobar sub segmental PEs in both lungs, PE was within the distal right main artery, pulmonary artery distal left main, left middle lobe, middle right lobe / upper right lower lobe and middle lobar, segmental and sub segmental pulmonary arteries. The patient also had pulmonary emboli in the distal left main pulmonary artery of left middle lobe and left lower lobe, pulmonary arteries. There was also some degree of right heart dysfunction which was diagnosed by contrast. On 15Mar2021, the patient also had right femoral vein emboli/ occlusive thrombus visualized in the right proximal femoral vein. The patient is in a nursing home, the doctor did not want to listen to the reporter because her brother is a</p>
COVID19 VACCINE	PFIZER\BIONTECH	1224924-1	65+ years	15-30 days	<p>I had emergency surgery to remove a femoral blood clot from my groin to the bottom of my left leg; This is a spontaneous report from a contactable consumer (patient). A 67-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in left arm on 17Mar2021 12:00 (Batch/Lot Number: EP6955) as single dose for covid-19 immunisation at a Pharmacy or Drug Store. Medical history included known allergies to sulfa drugs, latex, animal dander, dairy, wheat, mold, mildew, ragweed and other wildflowers; and clot once before in the same leg-left inner thigh in 1974. Concomitant medications included thyroid (ARMOUR THYROID) and apixaban (ELIQUIS). The patient previously had a pneumonia vaccine on 24Feb2021 in the left arm. The patient does not know if her first dose of Pfizer vaccine caused this, but on ""04Mar2010"" (as reported) she had an emergency surgery to remove a femoral blood clot from her groin to the bottom of her left leg which started on 03Apr2021 at 12 AM (as reported). The event resulted in emergency room/department or urgent care visit, hospitalization for 2 days and was considered life threatening illness (immediate risk of death from the event). She had a clot once before in the same leg-left inner thigh in 1974. The patient was on Eliquis 5 mg 2 pills 2 X day for two more days, then 1 pill in am and 1 pill in evening for rest of her life. The patient had the second dose of BNT162B2 (lot: ER8732) on 07Apr2021 in the left arm. The patient has no covid prior vaccination and was not tested for covid post vaccination. The event recovered with lasting effects.""</p>

COVID19 VACCINE	PFIZER\BIONTECH	1227273-1	40-49 years	15-30 days	massive clots; Pulmonary Embolisms; Occluded Left Lung, Right Ventricle; Occluded Left Lung, Right Ventricle; This is a spontaneous report from a contactable consumer (parent). A 44-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported) via an unspecified route of administration administered in the right arm on 15Mar2021 13:45 as a single dose for COVID-19 immunisation. Medical history included multiple sclerosis. The patient is not pregnant at the time of vaccination. The patient has no known allergies and has not had COVID prior to vaccination. Concomitant medications included gabapentin, carbamazepine (TEGRETOL), fluoxetine, colecalciferol (VITAMIN D), fish oil, and baclofen. The patient did not receive any other vaccine in 4 weeks prior to the COVID vaccine. On 30Mar2021 06:00, the patient experienced Pulmonary Embolisms, Occluded Left Lung, Right Ventricle and had emergency open heart surgery to remove massive clots. He coded for 4 minutes and was in ICU for 9 days. The patient was hospitalized due to the events on an unspecified date for 12 days. The events resulted in Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event), and Disability or permanent damage. Treatment for the events included open heart surgery. The patient underwent COVID test post vaccination via nasal swab on an unspecified date with unknown results. The outcome of the events was recovered with sequelae on an unspecified date. Information about lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1227961-1	65+ years	15-30 days	Pulmonary Embolism in right lung; This is a spontaneous report from a contactable consumer (patient). A 92-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/Lot Number: EL9267), via an unspecified route of administration, administered in right arm on 16Feb2021 at 12:45 PM at the age of 92-years-old as single dose for COVID-19 immunization. Facility type vaccine was reported as Other. The patient had no other vaccine in four weeks. The patient's medical history included known allergies to penicillin and sulfa drugs. Concomitant medications included fluoxetine, cyanocobalamin (B12-VITAMIN), and fish oil (OMEGA 3); all taken for unspecified indications, start and stop dates were not reported (reported as other medications in two weeks). The patient previously took potassium iodate and experienced allergies. The patient previously received the first dose of BNT162B2 in the right arm on 26Jan2021 at 12:45 PM (lot number: EL9261) at the age of 92-years-old for COVID-19 immunization. The patient experienced pulmonary embolism in right lung on 07Mar2021 at 09:00 AM. The event resulted in emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event). The patient was hospitalized for pulmonary embolism in right lung for 2 days in 2021. The patient received treatment for the event which included heparin. The patient had no COVID prior the vaccination and was not tested for COVID post vaccination. The outcome of the event was recovering.
COVID19 VACCINE	PFIZER\BIONTECH	1228481-1	50-59 years	15-30 days	The patient had previously been diagnosed with COVID-19 in November 2020, but did not require hospitalization and had recovered. He received his first dose of the Pfizer COVID vaccine on 2/25/2021, and on 3/15/2021, collapsed suddenly at home and was unable to be resuscitated. An autopsy was performed at the request of the family, and a massive pulmonary embolus was found in the main pulmonary artery and extending far into the segmental pulmonary arteries of both lungs.
COVID19 VACCINE	PFIZER\BIONTECH	1238440-1	65+ years	15-30 days	Patient presented to ED on 3/15/2021 with fatigue, subjective fevers, dry cough, and diarrhea found to have COVID pneumonia. CT PE negative at that time. Hospitalization complicated by RUE superficial cephalic vein thrombus, epistaxis, GIB, gluteal abscess, and AKI. Patient made DNR. Suspected cause of death: ventricular tachycardia secondary to renal failure and metabolic abnormalities in the setting of COVID ARDS.
COVID19 VACCINE	PFIZER\BIONTECH	1245306-1	65+ years	15-30 days	I got a blood clot, venous, in my upper right leg. Started on or about March 3rd, 2021

COVID19 VACCINE	PFIZER\BIONTECH	1254610-1	50-59 years	15-30 days	<p>DVT's in right calf; This is a spontaneous report from a contactable consumer (patient). A 57-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Batch/Lot number was not reported), dose 1 via an unspecified route of administration, in left arm on 16Mar2021 02:00 (at 57-years age) as single dose for covid-19 immunisation. Medical history included ongoing high blood pressure diagnosed in 2002 and it is under control with medications, ongoing diabetes diagnosed in 2000, neuropathy, allergies. The patient previously took first dose of BNT162B2 for Covid-19 immunization as Covid-19 vaccine first dose. Concomitant medications included metformin taken for diabetes mellitus from 2010 and ongoing at 1000 mg, twice a day; hydroxyzine (HYDROXYZINE) taken for allergies and ongoing at 25 mg, once a day; omeprazole (OMEPRAZOLE) taken for high blood pressure and ongoing at 40 mg, once a day; losartan (LOSARTAN) taken for hypertension and ongoing at 100 mg, once a day; carvedilol (CARVEDILOL) taken for high blood pressure and ongoing at 6.25 mg, twice a day; gabapentin (GABAPENTIN) taken for neuropathy and ongoing at 800 mg, twice a day; trazodone (TRAZODONE) taken for sleep and ongoing at 100 mg, once a day; simvastatin (SIMVASTATIN) at 20 mg, once a day taken for blood cholesterol and ongoing; insulin detemir (LEVEMIR) taken for diabetes mellitus and ongoing at 30 uL, once a day. Patient hopes he was not going to die. States on Saturday 3Apr2021 he went to the ER because he had DVT's in his right calf and they gave him the pneumonia vaccine there and he was under the influence because he was on pain medications. Patient received the pneumonia vaccine on Sunday 04Apr2021. NDC, lot number, or expiry date unknown. Caller states he got the second dose of the Pfizer vaccine today 6Apr2021. patient hopes he was not going to die because he took the two vaccines so close to each other. Patient has had DVT's since 2014 but flared up this Saturday 03Apr2021. States it was under control and it is recovering slowly, blood is flowing, INR is flowing, and it is therapeutic. they gave him a heparin drip to dissolve it in the ER. Patient was admitted to hospital at 12 midnight on 04Apr2021 and got out on 05Apr2021. The outcome of the event was resolving. Information on the lot/batch number has been requested.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1255233-1	65+ years	15-30 days	<p>infection; Abnormal nose bleed with blood cloths the first day; Abnormal nose bleed with blood cloths the first day/6 more nose bleed that it was taking me to control up to 30 min; This is a spontaneous report from a contactable other HCP (patient). A 75-year-old female patient (not pregnant) received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot Number: EN6207), via an unspecified route of administration on 15Mar2021 10:45 (at 75 years old, not pregnant), single dose for covid-19 immunisation. Medical history included Type II diabetes, Hypertension, GERD and hypercholesterilymia, sulfa allergy, all from an unknown date. Concomitant medications included verapamil; rosuvastatin calcium (CRESTOR); metformin; omeprazole, unspecified blood thinners. The patient previously took tetracycline for known allergies: Tetracycline. Patient experienced abnormal nose bleed with blood cloths the first day (reported as 30Mar2021 0130). Five days later in two days had 6 more nose bleed that it was taking me to control up to 30 min. She went to ER in the morning and had a CBC having results normal with normal levels of platelets. She was referred to PCP. She saw a NP next day and gave me referral to ENT specialist. Using an scope could not find anything and ordered to have CT Scan. Results show negative for polips, tumors and show only a shadow by eye socket which MD believe it was an infection that was leading to the bleed. Prescribe a very small amount of Amoxicilline 125 mg, twice a day for 7 days plus a saline gel. Patient had the last nose bleed at midnight. For 3 days did not have any bleeding until today, at 10:15 am, with heavy bleeding which took me 15 min. to control. She has no history of nose bleed, taking blood thinners, no head traumas either. No other vaccine in four weeks. No Covid prior vaccination. No Covid tested post vaccination. The outcome of the event infection was unknown, other events was not recovered.; Sender's Comments: Information provided was so limited to prevent a meaningful and definite medical assessment for the events. A causal relationship cannot be completely excluded for BNT162B2 injection and development of Thrombosis and Epistaxis, only based on a plausible chronological sequence. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1255628-1	Unknown	15-30 days	died yesterday due to blood clots; This is a spontaneous report from a contactable consumer. A 55-year-old female patient (mother) received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 28Mar2021 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient medical history and the patient's concomitant medications were not reported. The patient experienced blood clots and died due to the event. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested. ; Reported Cause(s) of Death: died yesterday due to blood clots
COVID19 VACCINE	PFIZER\BIONTECH	1255698-1	40-49 years	15-30 days	NSTEMI; Pulmonary Embolism; left upper arm thrombosis; This is a spontaneous report from a non-contactable other healthcare professional (patient). A 48-year-old male patient received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE), on 22Mar2021 (at the age of 48-years-old) at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. No other vaccine received in four weeks. On 15Apr21, the patient presented to hospital with complaints of dyspnea, chest pain and arm swelling. The patient was found to have left upper arm thrombosis, pulmonary embolism, and NSTEMI. The adverse events started on 15Apr2021 and resulted in emergency room/department or urgent care visit, hospitalization on 15Apr2021 and life-threatening illness (immediate risk of death from the events). An unspecified treatment was received in response to the events. The outcome of the events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.
COVID19 VACCINE	PFIZER\BIONTECH	1255715-1	65+ years	15-30 days	This is a spontaneous report from a contactable consumer. This 81-year-old female consumer (patient) reported that she received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number unknown) at single dose for COVID-19 immunisation on 13Jan2021. Relevant history included mild dementia, high cholesterol. Relevant concomitant drugs included memantine 10MG,donepezil 5MG,atorvastatin, cetirizine hydrochloride (ZYRTEC). The patient was not pregnant. No known allergies. On 30Jan2021, the patient fell and became unconscious after getting up from bed to use bathroom, was able to get up and go back to bed. Next day, 31Jan2021, she told her daughter at 2pm what had happened and daughter took her to urgent care. Urgent care was performed EKG and called ambulance as EKG suggested suspicious activity. She was coughing with blood. Cat scan of the lung revealed acute saddle pulmonary embolism with acute cor pulmonale and a large blood clot in the calf. On 02Feb201 then placed her on blood thinner and discharged her. As soon as arrived home, she began to suffer a massive gastro intestinal bleed and was rushed back to the hospital. On 04Feb2021, she began to have heart issues and suffered a mild heart attack and underwent a procedure to have a stent inserted. She developed the shingles the next day (05Feb2021). The events assessed as serious due to Hospitalization, Life threatening illness (immediate risk of death from the event), Disability or permanent damage. The patient visited Emergency room/department or urgent care. The outcome of events was resolved with sequel. Treatment therapy involved. The patient was not diagnosed with COVID prior vaccination. The patient had Nasal Swab/Fast Test/PCR (for COVID) in Apr2021 with negative result. Information on the lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1259454-1	50-59 years	15-30 days	venous sinus thrombosis of the superior sagittal sinus, based on imaging likely occurred 1-2 weeks prior to presentation, ~ 1-3 weeks after vaccination no other clear reason for hypercoag state, no prior thromboembolic events, no h/o malignancy or rheumatological disease.

COVID19 VACCINE	PFIZER\BIONTECH	1261823-1	65+ years	15-30 days	<p>had large bilateral PE; This is a spontaneous report from a contactable nurse. A 72-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly on 23Jan2021 (lot number EL1283) on Left arm at single dose for COVID-19 immunization. Facility type vaccine was at urgent care center. Medical history included hypertension. Concomitant medications were not reported. The patient had large bilateral PE (pulmonary embolism) several weeks after vaccine on 18Feb2021. The event resulted in emergency room visit, physician office visit and Hospitalization for 2 days. Serious criteria Life-threatening also reported for the event. The event was treatment with anticoagulation. The outcome of the event was resolved in 2021.; Sender's Comments: A causal relationship between the event ""had large bilateral PE"" and suspect product BNT162B2 is possible based on the information provided and a temporal association in this 72-year-old female patient with hypertension. This case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified.""</p>
COVID19 VACCINE	PFIZER\BIONTECH	1261827-1	60-64 years	15-30 days	<p>Pulmonary embolism; This is a spontaneous report from a contactable consumer (patient). A 60-year-old patient of unspecified gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6199) in the left arm on 30Mar2021 02:00 PM at 60-year-old at single dose for COVID-19 immunisation. Medical history included allergies to orphenadrine citrate (NORFLEX), blue dye. Other medical history included myasthenia gravis (Mg), asthma, hyperbaric oxygen therapy (hbo), glaucoma. There was no covid prior vaccination. There was no other vaccine in four weeks. There were concomitant medications in two weeks (unspecified). Patient experienced adverse event: pulmonary embolism on 14Apr2021 04:00 PM. The adverse events resulted in: Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event). Hospitalization for 4 days. Patient received treatment for events included heparin drip. CT scan, respiratory TX, lab, apixaban (ELIQUIS). No covid tested post vaccination. Patient was recovering.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1261865-1	65+ years	15-30 days	<p>Death after experiencing blood clot to the lung</p>

COVID19 VACCINE	PFIZER\BIONTECH	1265948-1	50-59 years	15-30 days	<p>Pulmonary embolism; Shortness of breath; she tested positive for Covid; she tested positive for Covid; This is a spontaneous report from a contactable consumer (patient) via Pfizer sponsored program. A 52-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) (at 52 years of age), dose 1 via an unspecified route of administration on 20Mar2021 12:00 (Batch/Lot Number: ER8727; Expiration Date: 31Jul2021) as a single dose for COVID-19 immunisation. Medical history included allergies wherein she mentioned that her allergies were acting up so she took Tylenol 500mg, 1 pill; and insomnia. Concomitant medications included paracetamol (TYLENOL) taken for hypersensitivity; cetirizine hydrochloride, pseudoephedrine hydrochloride (ZYRTEC DUO) taken for hypersensitivity, start and stop date were not reported; and dextromethorphan hydrobromide, doxylamine succinate, ephedrine sulfate, ethanol, paracetamol (NYQUIL) taken for insomnia (it helps her sleep at night), start and stop date were not reported. It was reported that the patient already received 1st dose of the Pfizer-BioNTech Covid-19 Vaccine and was scheduled to receive the 2nd dose on 17Apr2021. Yesterday, she tested positive for Covid and got hospitalized. She said she got discharged today and is now on medication which includes a blood thinner. She wanted to know if she needed to reschedule her 2nd dose, and how. It was clarified that the patient had Covid test on 12Apr2021 with Positive result. She mentioned that she was reading paperwork and it said something about to let her vaccination provider know about medical conditions, allergies, bleeding or if she take blood thinners. She stated that she was prescribed blood thinners yesterday evening and she was going to be taking them for 3-6 months. She questioned if it was going to affect if she takes the shot on Saturday. She added that she will be on the blood thinner 5-6 days by then. She stated that she was tested for Covid in the hospital that she went in with shortness of breath and they did the test yesterday. She had shortness of breath Saturday (09Apr2021) and she went to the ER on 12Apr2021 and was admitted and was released 13Apr2021. She stated that she was diagnosed from being discharged with blood clots and she is now on a blood thinner and a steroid pill for inflammation. She clarified that she was diagnosed on 12Apr2021 with pulmonary embolism and was put on ELIQUIS and will take it for the 1st 7 days, 2 tablets twice a day and they are 5mg each and then she will take 1 tablet twice a day until she follows up with her primary doctor and will either stop taking it at 3 months or 6 months. She will also be taking Dexamethasone 2mg tablet taking 3 tablets once a day for 8 days. She stated that they did a C scan to identify blood clots. There was no other vaccine administered on the same date the Pfizer vaccine was given. The outcome of events was unknown.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1265958-1	30-39 years	15-30 days	<p>Developed blood clot in right leg (behind knee); This is a spontaneous report from a contactable consumer (patient). A 34-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not provided), via an unspecified route of administration, administered in Arm Left first dose on 26Feb2021 11:15 at single dose for covid-19 immunisation. The patient's medical history included Developed blood clots after twin c section. The patient has been off blood thinners for 2.5 years. The patient was not pregnant at time of vaccination. The patient's concomitant medications included venlafaxine hydrochloride (EFFEXOR) and vitamin d [vitamin d nos]. On 17Mar2021, the patient Developed blood clot in right leg (behind knee). The patient was put on blood thinners as treatment. The events cause the patient emergency room visit and physician office visit. The outcome of the event was recovering. Information on the lot/batch number has been requested.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1265977-1	65+ years	15-30 days	blood clot in her lung; Shortness of breath; blood pressure dropped extremely low; blood pressure fluctuates; This is a spontaneous report from a contactable consumer (patient). A 69-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection; Batch/Lot Number: EL3247), via an unspecified route of administration, administered in the left arm on 17Mar2021 at the age of 69-years-old as single dose for COVID-19 immunization. The patient had no medical history. There were no concomitant medications. The patient previously received the first dose of BNT162B2 on 24Feb2021 (Batch/Lot number was not reported) at the age of 69-years-old for COVID-19 immunization. On 07Apr2021, the patient experienced shortness of breath and blood dropped extremely low. On 08Apr2021, the patient experienced blood clot in her lung. And on Apr2021, the patient experienced blood pressure fluctuates. The patient had her final Pfizer Covid vaccine on 17Mar2021. The patient reported that she had to go to the hospital for shortness of breath and her blood pressure dropped extremely low. She stated that they did tests and found out she had a blood clot in her lung. The patient reported that she came home Sunday evening and took the drip thing out and started her on blood thinner that started with an E (as reported). The patient stated that she was told her cardiologist told her to report this. The patient wanted to know if there have been any other reports called in about people calling in with blood clots. The patient was hospitalized due to events shortness of breath, blood dropped extremely low, and blood clot in her lung from 08Apr2021 to 11Apr2021. The patient reported that her blood pressure fluctuates. She stated that it was better than when she was in the hospital. They gave her the drip. The patient reported that her values did come down and this was the only thing they could go by. The outcome of the events shortness of breath and blood pressure dropped extremely low was recovering. The outcome of the events blood clot in her lung and blood pressure fluctuates was unknown.
COVID19 VACCINE	PFIZER\BIONTECH	1265999-1	60-64 years	15-30 days	DVT Right Leg; This is a spontaneous report from a contactable other healthcare professional (patient). A 60-year-old female patient received second dose bnt162b2 (BNT162B2), via an unspecified route of administration, administered in right arm on 04Feb2021 08:30 (Lot Number: EL1283), at the age of 60-years at vaccination, as SINGLE DOSE for covid-19 immunisation. Medical history included osteoarthritis, asthma, fibromyalgia. Historical vaccine includes first dose of BNT162B2, Lot number: EL1283, on 14Jan2021 08:45 AM in left arm at the age of 60-years. The patient is not pregnant at the time of vaccination. The patient did not have COVID-19 prior vaccination. Concomitant medications included etodolac (LODINE); montelukast; amitriptyline; acetylsalicylic acid (BREOPRIN), all were taken for unspecified indication, start and stop date were not reported. The patient previously took Vioxx and experienced allergies. The patient experienced DVT on right leg on 21Feb2021 with outcome of recovered. The event required physician office visit. The patient has not been tested for COVID-19 post vaccination. Therapeutic measures were taken as a result of DVT in right leg which includes Eliquis.
COVID19 VACCINE	PFIZER\BIONTECH	1269722-1	18-29 years	15-30 days	had two blood clots on her lungs; This is a spontaneous report from a contactable consumer. A 20-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose at the age of 20-years-old via an unspecified route of administration, administered in arm left on 28Mar2021 12:30 (Batch/Lot Number: ER8730) as single dose for covid-19 immunisation. Medical history included birth control from an unknown date and unknown if ongoing. Concomitant medication included ethinylestradiol, norgestimate (SPRINTEC) taken for birth control from Dec2020 to 12Apr2021. The patient experienced had two blood clots on her lungs on 12Apr2021 18:00. The patient was hospitalized due to the event from 12Apr2021 to 14Apr2021. The patient was recovering from the event.
COVID19 VACCINE	PFIZER\BIONTECH	1275726-1	65+ years	15-30 days	massive Pulmonary embolism causing cardiac arrest

COVID19 VACCINE	PFIZER\BIONTECH	1278723-1	40-49 years	15-30 days	three blood clots in right leg; This is a spontaneous report from a contactable consumer. A 45-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: ER2613, Expiry date not reported), via an unspecified route of administration, administered in the left arm on 25Mar2021 15:00 (age at vaccination was 45 years) as single dose for COVID-19 immunization. Medical history included drug hypersensitivity (sulfonamide allergy) from an unknown date and unknown if ongoing, and seasonal allergy from an unknown date and unknown if ongoing. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was vaccinated at a clinic. The patient was not diagnosed with COVID-19 prior to vaccination. Since the vaccination, the patient has not been tested for COVID-19. Concomitant medications included fluticasone propionate taken for an unspecified indication, start and stop date were not reported; olopatadine hydrochloride (PATADAY) taken for seasonal allergy, start and stop date were not reported. The patient experienced three blood clots in right leg on 09Apr2021 20:00 with outcome of recovering. Therapeutic measures were taken as a result of three blood clots in right leg (thrombosis) that included blood thinners (Eliquis). The event was reported as serious, medically significant. No follow-up attempts are possible. No further information is expected.
COVID19 VACCINE	PFIZER\BIONTECH	1278908-1	50-59 years	15-30 days	A Blood clot was found; Cellulitis; Migraine started within 24 hours; left calf pain/Leg increased in swelling and burning pain; severe swelling and burning sensation; severe swelling and burning sensation; Leg increased in swelling and burning pain; Phlebitis; This is a spontaneous report from a contactable consumer (patient). A 50-year-old female patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number: EN6199/EN5318), via an unspecified route of administration administered in left arm at doctor's office/urgent care facility on 12Mar2021 15:00 as SINGLE DOSE for COVID-19 immunisation. The patient was not pregnant at the time of vaccination. The patient was not COVID tested post vaccination. The patient had no other vaccines in four weeks. Medical history included high blood pressure and sleep apnea. Concomitant medications included amoxicillin, valsartan, amlodipine, and vitamin d [vitamin d nos]. The patient previously took doxycycline and experienced allergies. Historical vaccine includes first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) on an unspecified date for COVID-19 immunisation. On 05Apr2021 at 03:00 PM, the patient experienced a blood clot was found, cellulitis, migraine started within 24 hours, left calf pain/leg increased in swelling and burning pain, severe swelling and burning sensation, leg increased in swelling and burning pain, and phlebitis. It was further reported that migraine started within 24 hours. 48 hour left calf pain that got increasingly worse leading to a severe swelling and burning sensation. The patient went to right time urgent care on Friday, 09Apr2021. The patient was diagnosed with cellulitis. It was also reported that pain increased swelling spread and went to emergency room (ER) on 10Apr2021 for ultrasound of leg. No clots and was advised if worsened to come back. The patient's leg increased in swelling and burning pain. The patient went to urgent care patient first on 11Apr2021 and then the doctor on Monday, 12Apr2021 where she was sent for a STAT ultrasound due to major pain and swelling. A blood clot was found. Phlebitis was diagnosis. The patient was sent to a vascular surgeon on 13Apr2021 and vein specialist on 15Apr2021. The patient was given Xarelto blood thinners and started taking them on 15Apr2021. All of this began 48 hours after taking the second vaccination (pending clarification) and has the patient worried. The events resulted to doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. Therapeutic measures were taken as a result of all events. The patient had not yet recovered from all events.
COVID19 VACCINE	PFIZER\BIONTECH	1284832-1	65+ years	15-30 days	Big Blood Clot in left leg; This is a spontaneous report from a non-contactable consumer (Patient). A 80-years-old female patient (Non-pregnant) received bnt162b2 (Pfizer-Biontech COVID-19 vaccine, Solution for injection), via an unspecified route of administration on 28Mar2021 11:00 as single dose for COVID-19 immunisation. The patient medical history included allergies to Demerol. The patient's concomitant medications were not reported. On 17Apr2021 21:30 patient experienced big blood clot in left leg. Patient was hospitalized for 2 days. The patient underwent lab tests and procedures which included Nasal swab test results negative on 16Apr2021. Treatment received for the adverse event was blood thinners. The outcome of event was Not recovered. No follow-up attempts are possible; information about lot/batch number cannot be obtained

COVID19 VACCINE	PFIZER\BIONTECH	1284856-1	50-59 years	15-30 days	5-6 Blood clots, blood clots were present; heart attack; This is a spontaneous report from a contactable consumer reporting for himself. A 54-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Mar2021 12:00 on left arm at single dose for COVID-19 immunization. Facility type vaccine was at Pharmacy or Drug Store. Medical history included high blood pressure, high cholesterol. Concomitant medications included atorvastatin (LIPITOR), amlodipine besilate (NORVASC). Historical Vaccine included first dose of BNT162B2 on 08Mar2021 12:00 on left arm for COVID-19 immunization. The patient experienced 5-6 Blood clots, had heart attack and blood clots were present on 14Apr2021 13:00. The events were resulted in Emergency Room Visit, Hospitalization, Life threatening illness (immediate risk of death from the event). Treatment was received for the events included Stent. The outcome of the events were resolving. Information on Lot/Batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1288353-1	65+ years	15-30 days	may be blood clot; Something happened with my knee and it has just got worse; I was thinking maybe it is a pulled muscle or something but it is very bad now; This is a spontaneous report received from a contactable consumer (patient). An 83-year-old female patient (5 feet 1 inches, about 120 pounds) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EN6198, patient was not sure) via an unspecified route of administration at left arm on 22Feb2021 (83-year-old at time of vaccination), at single dose; the second dose of BNT162B2 (lot number: unknown) via an unspecified route of administration on 15Mar2021 (83-year-old at time of vaccination), at single dose, for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Patient stated she has got both the shots of Pfizer (Covid-19 vaccine) and at the end of the first one or it is like eighteen days, just before the second shot, something happened with her knee and it has just got worse (from 12Mar2021). She did not connect that with the Pfizer shot and I was thinking maybe it is a pulled muscle or something but it is very bad now. She would like to know what she can do. Also, she is thinking may be blood clot at this point and she would like to have it checked. She thinks that she should be able to contact somebody to actually get some physical test on this. She tried heat and cold alternate and Absorbine Jr. and Aspirin. It varied with the days, she thinks she has taken Aspirin about twice a day and it is a tablet and it was 325 mg and she took two of those, orally. Therapeutic measures were taken as a result of the event and included ""heat and cold alternate and Absorbine Jr. and Aspirin"". The outcome of the event was not recovered. Information on the lot/batch number has been requested.""
COVID19 VACCINE	PFIZER\BIONTECH	1288382-1	40-49 years	15-30 days	Hospitalized 18Apr2021 with bilateral Pulmonary embolism; This is a spontaneous report received from a contactable nurse (who is also the patient). A 42-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date unknown), via an unspecified route of administration in the left arm, on 02Apr2021 11:00, as single dose, for COVID-19 immunisation, at a pharmacy/drug store. Medical history included esophageal dysmotility, thyroid nodules, ACL tear and ACL repair on 15Apr2021. The patient did not have COVID-19 prior to vaccination. The patient was not pregnant at the time of vaccination. Concomitant medications included escitalopram oxalate (LEXAPRO); and paracetamol (TYLENOL), both taken for unspecified indications, start and stop dates were not reported. The patient previously took prochlorperazine (COMPAZINE) and experienced allergies. Historical vaccine included the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number was not reported) at age 42 years, via an unspecified route of administration in the left arm, on 19Mar2021, for COVID-19 immunisation. The patient did not receive other vaccines in four weeks. The patient was hospitalized on 18Apr2021 with bilateral pulmonary embolism (onset date was 18Apr2021). Treatment for the event included Lovenix. The patient underwent COVID nasal swab on 05Apr2021 and 18Apr2021 which both resulted to negative. The outcome of the event was not recovered. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect BNT162B2 cannot be excluded for the reported bilateral pulmonary embolism occurred in a plausible temporal relationship. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.

COVID19 VACCINE	PFIZER\BIONTECH	1288454-1	18-29 years	15-30 days	1 pulmonary embolism in the left lung, 2 pulmonary embolisms in my right lung; a slight pleural effusion in the right lower lung; This is a spontaneous report from a contactable consumer (patient). A 22-year-old female patient received second dose of BNT162B2 (Lot Number: EM9809), via an unspecified route of administration, administered in the left arm on 13Mar2021 14:00 at 22 years-old, as a single dose for COVID-19 immunisation. Medical history included Known Allergies: Penicillin and COVID-19, both on an unknown date. Concomitant medications included ethinylestradiol, levonorgestrel (CAMRESE LO) taken for an unspecified indication, start and stop date were not reported; ergocalciferol (VIT D) taken for an unspecified indication, start and stop date were not reported; escitalopram oxalate (LEXAPRO) taken for an unspecified indication, start and stop date were not reported. The patient previously took amoxicillin, diphenhydramine (BENADRYL), xylometazoline hydrochloride (SUDAFED), guaifenesin and all experienced allergies. The patient previously received first dose of BNT162B2 (Lot Number: EM9809), via an unspecified route of administration, administered in the left arm on 20Feb2021 14:00 at 22 years old as single dose for COVID-19 immunisation. On 05Apr2021 18:00, the patient experienced 1 pulmonary embolism in the left lung, 2 pulmonary embolisms in the right lung and a slight pleural effusion in the right lower lung. The events resulted in doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care and considered as a life threatening illness. The patient was not pregnant at the time of vaccination. Prior to the vaccination, the patient was diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. Therapeutic measures were taken as a result of all the events which included Xarelto and Hydrocodone. The outcome of the events was recovering.
COVID19 VACCINE	PFIZER\BIONTECH	1294746-1	60-64 years	15-30 days	blood clots; urinating blood; arm pain; fatigue; he started bleeding from the second one; This is a spontaneous report from a contactable consumer, the patient. This 63-year-old male patient reported that he received the second dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot Number: EN6206) on 17Mar2021 (at the age of 63-years-old) via unspecified route as a single dose for COVID-19 immunization. Medical history included enlarged prostate, urinary health issues (gets up in the middle of the night), has glasses as he had cataract surgery last year (2020) so he lost his close-up vision. Concomitant medications were not reported. The patient previously received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Batch/lot number: EL3249) on 18Feb2021 (also reported as 17Feb2021) (at the age of 63-years-old) via unspecified route as a single dose for COVID-19 immunization and experienced urinating blood and blood clots profusely, UTI, bleeding, arm pain, and fatigue. The patient received his second shot on 17Mar2021 and almost to the date three weeks later, had the same incident with urinating blood and passing blood clots. He waited an extra day because he could not go to the bathroom and then he went to the ER that same day so that they could flush him out. He also had an appointment on that same day with his urologist. A CT scan was done at the ER and then in the afternoon he went to the doctor. The doctor did a catheter flush. The patient was unclogged but he was passing blood. The patient also reported that he did have the normal arm pain and fatigue the second day or the day after the shot. He has no other adverse reactions at this time. The patient reported 11Apr2021 or 12Apr2021 was when he started bleeding from the second one (shot). He went to the hospital on 14Apr2021. The patient confirmed he was not admitted. The patient reported he is going to the doctor today (21Apr2021) to see the urologist but the urologist is going to do a scope in his bladder because that is the only thing that they cannot see. The clinical outcome of the events urinating blood, blood clots, bleeding, arm pain, and fatigue was unknown. The patient stated he does not know if this is an issue, however, it coincided with both of his shots. The patient was calling to see if this is something that has been seen or if it is in his head.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021470922 same patient/reporter, different AE/first dose
COVID19 VACCINE	UNKNOWN MANUFACTURER	1245000-1	65+ years	15-30 days	Blood clots in the lungs, pulmonary embolism
COVID19 VACCINE	JANSSEN	1207818-1	65+ years	31-60 days	Flank chest pain (pain under right rib cage) and Dyspnea on exertion; woke pt up at 0300 on 4/9/21 Chest pain with deep breathing., fever, and nausea upon presentation to ED Pt denied recent travel or prolonged immobilization Patient diagnosed with bilateral pulmonary embolism per CTA

COVID19 VACCINE	JANSEN	1207905-1	Unknown	31-60 days	<p>Patient admitted on 4/9/21 (unsure where they received J&amp;J COVID vaccine on 3/6/21) Per clinical pharmacist internal event report: Pt received Johnson and Johnson Covid vaccine on 3/6/21. Has chronic subdural hematomas FYI (seen on scans in Feb). Patient is a 80 y.o. female patient who presented with complaints of dyspnea and BLE edema and was admitted with a principal diagnosis of Acute on chronic congestive heart failure with left ventricular diastolic dysfunction (HCC). Cardiology consulted. Initially diuresed however became hypotensive. Patient had episode of slurred speech and disorientation on 4/11. Code stroke called. CTH with stable SDH. CTA of head had no acute cerebral occlusion. Incidentally was found to have bilateral PEs on CTA h/n. Full CTA chest ordered for further evaluation, noted extensive bilateral pulmonary emboli, associated with Rt heart strain. She was started on heparin drip, Dr. cleared with neurosurgery prior to starting on 4/11 given subacute SDH which has been stable on imaging. Heparin transitioned to eliquis. Additional chart information: ht: 5'4"" weight: 108.3 kg CrCl: 50.3 mL/min platelets since admission: 160 - 173 Admission Diagnosis: Acute on chronic congestive heart failure, unspecified heart failure type (HCC) [I50.9] Expected discharge: 4/14/21 Active Problems: Hypertension associated with diabetes (HCC) Gastroesophageal reflux disease without esophagitis Non-insulin dependent type 2 diabetes mellitus (HCC) Seizure disorder (HCC) Dyslipidemia associated with type 2 diabetes mellitus (HCC) OSA on CPAP Pulmonary hypertension due to left ventricular diastolic dysfunction (HCC) Subdural hematoma (HCC) Class 2 obesity due to excess calories in adult Dizziness Acute on chronic diastolic CHF (congestive heart failure) (HCC) Hospital course: Patient is a 80 y.o. female patient who presented with complaints of dyspnea and BLE edema and was admitted with a principal diagnosis of Acute on chronic congestive heart failure with left ventricular diastolic dysfunction (HCC). Cardiology consulted. Initially diuresed however became hypotensive. Patient had episode of slurred speech and disorientation on 4/11. Code stroke called. CTH with stable SDH. CTA no acute occlusion. Suspecting breakthrough seizure. Neuro consulting, EEG normal. Titrating up zonegran - patient will discharge on 100mg in AM and 200mg in PM. Incidentally was found to have bilateral PEs on CTA h/n. Full CTA chest ordered for further evaluation, noted extensive bilateral pulmonary emboli, associated with Rt heart strain. She was started on heparin drip, Dr. cleared with neurosurgery prior to starting on 4/11 given subacute SDH which has been stable on imaging. Heparin transitioned to eliquis. Will need to follow up with PCP. Valsartan was held on admission for hypotension. Blood pressure has remained well controlled off of all antihypertensives. She will need to follow up with PCP for further management of BP, may need valsartan resumed in near future. Patient is medically stable for discharge to home.""</p>
COVID19 VACCINE	JANSEN	1207980-1	60-64 years	31-60 days	<p>The patient presented 3 weeks post injection with cardiac arrest from home. She had a 1 hour downtime. The day previous she had worsening leg swelling and SOB +DOE. Post arrest she was diagnosed with massive PE. She was treated for PE with thrombolytics and improved hemodynamically. She unfortunately at this time has anoxic brain injury.</p>
COVID19 VACCINE	JANSEN	1209700-1	65+ years	31-60 days	<p>Dyspnea developed one day after vaccination. Symptoms have persisted until today, when she presented to office</p>
COVID19 VACCINE	JANSEN	1211237-1	50-59 years	31-60 days	<p>Presented to urgent care clinic on 4/3/21 with a chief complain of leg pain (Calf to lower left extremity for several days prior to presentation). A vascular ultrasound was performed, confirming the presence of an acute thrombus in the left leg. The patient was written a prescription for apixaban and discharged to his primary care provider for follow up.</p>
COVID19 VACCINE	JANSEN	1212461-1	50-59 years	31-60 days	<p>On 4/15/2021 patient presented with chest pain and left lower extremity pain, which started about 2 days prior to admission. CTA showed large volume multifocal bilateral pulmonary emboli throughout numerous right lower lobe, right middle lobe, right upper lobe, left upper lobe, and left lower lobe segmental branches. Left lower extremity venous ultrasound showed no evidence of deep or superficial vein thrombosis; the right lower extremity was not scanned. Patient denies personal or family history of VTE. She states that she does not smoke and has no history of smoking. Patient was treated with apixaban 10 mg po BID x7 d followed by 5 mg po BID. Platelets were 295 on admission.</p>
COVID19 VACCINE	JANSEN	1213087-1	40-49 years	31-60 days	<p>1 Extensive left upper extremity venous thromboembolism-nonocclusive in the left subclavian, left axillary, brachial and basilic veins 2 Right lower lobe subsegmental PE 3 Mechanical thrombectomy of the left subclavian and axillary veins 4 Bruising all over body</p>

COVID19 VACCINE	JANSSSEN	1213215-1	50-59 years	31-60 days	On 3/12/21 developed pain in left calf area. Pain continued to progress and became extremely painful by April 2, 2021. April 3rd went to urgent care for assessment. Sent from urgent care to Lab for ultrasound of left calf which came back positive for DVT. Sent to ER and started on IV heparin. Also received CT Scan of Chest and Abdomen which showed PE in right lower lobe of lung. Admitted to Vascular unit. Doctor ordered an upper Endoscopy to check for bleeding due to low HGB and FE. The Scope was negative for bleeding. Lab work was ordered on 04/06/21 and due to very low HGB and FE patient was given an FE (iron) infusion the evening of 4/06/21 and again the morning of 04/07/21. The patient also received a unit of blood the morning of 04/07/21 prior to being discharged from the hospital. Patient was started on Eliquis 5mg 2x a day, Ferrus Sulfate 325mg 1x a day and Omeprazole 20mg 1x a day as discharge medications.
COVID19 VACCINE	JANSSSEN	1214248-1	30-39 years	31-60 days	Patient presented with new onset dvt 5 wks post covid 19 vaccination. 36 yr old female with solitary risk factor of previous history of DVT. Of note, pt had dvt in 2002 which occurred while on birth control (and pt became pregnant).
COVID19 VACCINE	JANSSSEN	1215073-1	65+ years	31-60 days	On 4/10/21 to Urgent Care. Found blood clots in my lungs and Pneumonia, Clots removed at Hospital on 4/11/21. Hospitalized until 4/13/21. Treatment - blood thinners (enoxaparin, heprin and steroids), azithromycin, Advair disk, albuterol, Spiriva, Symbicort Outcome: Still trouble breathing, slow moving and sore from the incision.
COVID19 VACCINE	JANSSSEN	1220696-1	65+ years	31-60 days	vaccine 3/7/21. 4/9/21 presented in ER with leg pain. dx with dvt. has no prior hx or fam hx of clots. is not a smoker. is on hrt. treating dvt with eliquis.
COVID19 VACCINE	JANSSSEN	1223667-1	65+ years	31-60 days	Blood clots - minor stroke
COVID19 VACCINE	JANSSSEN	1230341-1	40-49 years	31-60 days	According to patient, she woke up at 2:00 a.m. to use the restroom and noticed she had a very dry mouth and was thirsty. She passed out and when she came to she experienced decreased vision. She was taken to the emergency room via ambulance for tests. She was diagnosed with a blood clot to her lungs after CT scans. She also had additional scans and blood work and stayed at Hospital in town (I am having trouble adding this to the shaded area in question 21).
COVID19 VACCINE	JANSSSEN	1231031-1	65+ years	31-60 days	Diagnosed with PE/DVT without any previous history of this and no significant RF for this.
COVID19 VACCINE	JANSSSEN	1234108-1	50-59 years	31-60 days	Went to the hospital with chest pain. They performed a catheter to check for blockages and instead found an extremely rare blood clot that ultimately caused a mild heart attack.
COVID19 VACCINE	JANSSSEN	1236311-1	60-64 years	31-60 days	Pulmonary embolism
COVID19 VACCINE	JANSSSEN	1237450-1	30-39 years	31-60 days	DVT right ulnar vein 4/6/21
COVID19 VACCINE	JANSSSEN	1237941-1	60-64 years	31-60 days	Patient presented to the ER with chest pain, non radiating, heavy weight. Patient was found to have acute DVT.
COVID19 VACCINE	JANSSSEN	1238061-1	30-39 years	31-60 days	Blood clot
COVID19 VACCINE	JANSSSEN	1238387-1	65+ years	31-60 days	pulmonary embolism with chest pain symptoms on 4/9, improved with anticoagulation. Patient also had laparoscopic paraesophageal hernia repair on 3/25 and so could also have been a provoked pulmonary embolism.
COVID19 VACCINE	JANSSSEN	1238801-1	65+ years	31-60 days	Patient stated receiving J&J vaccine on 03/19/21. Patient came to ER with acute DVT in left lower extremity on 04/21/2021.
COVID19 VACCINE	JANSSSEN	1238916-1	60-64 years	31-60 days	Pt has a history of DM2, HTN, HLD, HCV cirrhosis (sp treatment, Child Pugh A), CKD3 with baseline Cr 1.5 who presented to the ER after a syncopal episode and with headaches. She has no history of a positive COVID test. She reported receiving the J&J vaccine on 3/6 and reports headaches since then. She also had a syncopal episode that prompted her presentation to the ED. She underwent MRV of the brain looking for sinus thrombosis. The brain portion was normal but she was found to have a IJ thrombus. She denies prior history of VTE. It is overall unclear if this thrombus is related to her symptoms, to the vaccine, or completely incidental. Pt was started on a heparin drip in the hospital...
COVID19 VACCINE	JANSSSEN	1239051-1	60-64 years	31-60 days	2 weeks and 2 days after receiving the vaccination I had a blood clot blown from my nose no before issues with a bloody nose and not after it was a large blood clot there was not any continued bleeding before or after. Also where the shot was given is still sore in that area and does not seem to get better this is my right arm I am exercising and not any improvement.

COVID19 VACCINE	JANSSEN	1242694-1	50-59 years	31-60 days	03/19/21 woke up with numbness on whole right side of body (head to toe). Referred to ER by Family Physician on 03/20/21. admitted to hospital for testing. MRI confirmed a blood clot caused a Lacuna Infarcts Event (type of mini stroke) The patient continues to have numbness and difficulty walking, driving and has affected her normal daily activities. The patient will be required to start Plavix and baby aspirin. Waiting for requirement for Prolong numbness which affects her daily activity.
COVID19 VACCINE	JANSSEN	1243087-1	65+ years	31-60 days	Cortical sinus thrombosis with intracerebral hemorrhage, seizures. Admitted to ICU.
COVID19 VACCINE	JANSSEN	1243533-1	60-64 years	31-60 days	4 weeks following vaccine - DVT of the left lower leg.
COVID19 VACCINE	JANSSEN	1243751-1	65+ years	31-60 days	DVT to left arm, pt came to appt reporting left arm redness and swelling. Sent to hospital for venous doppler ultrasound that confirmed DVT to site. Pt started on blood thinners at this time.
COVID19 VACCINE	JANSSEN	1244000-1	50-59 years	31-60 days	Swelling in ankle, then in right leg.
COVID19 VACCINE	JANSSEN	1244543-1	50-59 years	31-60 days	Patient received J & J vaccine on 3/12/21. PCP states patient was admitted 4/21/21 with Pulmonary Embolism
COVID19 VACCINE	JANSSEN	1244983-1	50-59 years	31-60 days	Experienced blood clots in my nose every night for about 10 nights after receiving vaccine injection. Didn't think anything of it until I mentioned it to my mom who received her vaccine at the same time & place from the SAME BOTTLE and she too was waking with bloody clots in her nose. I experienced a reoccurrence for 4 days in mid April. I wouldn't have said anything but friends nagged us after the J&J blood clotting issue. (We both also experienced severe piercing & throbbing pain in the bone beneath the injection for about 14 days.) I mentioned both events to my GP on 3/26/21
COVID19 VACCINE	JANSSEN	1247921-1	65+ years	31-60 days	4/15/2021 approximately 1030 am client found to be AMS, non-responsive, aphasic, aphagic, left-sided facial droop, teeth clenched, left eye closes, right eye with deviated gaze. 911 called, client to hospital ER, work up/evaluation, admission for stroke related to blood clots found left frontal and right temporal lobes, per spouse. Client discharged 4 days later to home s/p CVA, bed-bound, remains aphasic, aphagic, non-communicative, no response to verbal stimuli. PLEASE NOTE: hospital admission. Unable to complete section 21. Admit for 4 days.
COVID19 VACCINE	JANSSEN	1248330-1	65+ years	31-60 days	Patient has leg cramps starting on Monday, April 19th. She went to the hospital at later date. Doctor diagnosed her with leg clot.
COVID19 VACCINE	JANSSEN	1257187-1	65+ years	31-60 days	Patient family called on 4/23/2021 and reported that patient was hospitalized on April 9th and 13th , 2021 for blood clot in the lungs after taking the Johnson & Johnson covid-19 vaccine on 3/09/2021. During the time of the report patient's family state that patient was stable and she is doing okay.
COVID19 VACCINE	JANSSEN	1257659-1	65+ years	31-60 days	Acute occlusive deep vein thrombosis noted in the left proximal and mid femoral and gastrocnemius veins. There is also evidence of acute partially occlusive deep vein thrombosis noted in the left common femoral and distal femoral veins. Patient was initially started on enoxaparin transitioned to apixiban for discharge.
COVID19 VACCINE	JANSSEN	1258420-1	65+ years	31-60 days	Patient received covid-19 vaccine in left arm on March 9th. He alerted health care provider of left arm swelling on April 19th that started 4-5 days prior. There was no redness or warmth, reported as non pitting left arm swelling. Venous duplex revealed Left upper extremity DVT predominately effecting subclavian and axillary vein.
COVID19 VACCINE	JANSSEN	1258629-1	65+ years	31-60 days	Blood clots in the left leg and in the lungs.
COVID19 VACCINE	JANSSEN	1259504-1	60-64 years	31-60 days	1 week post vaccine had 1 day with a sore throat and runny nose. Developed right calf pain 04/19/2021. Presented to ER on 04/25/2021 w/ a 2 day history of shortness of breath and some chest tightness worse with exertion, with worsening symptoms at time of ER visit. Admitted for observation with ""Pulmonary embolism without acute cor pulmonale and Acute respiratory failure with hypoxia""
COVID19 VACCINE	JANSSEN	1262422-1	65+ years	31-60 days	RESIDENT COMPAINED OF PAIN TO BILATERAL THIGHS AND LOWER BACK SENT TO ER. NOTIFIED BY ER, PATIENT HAS BLOOD CLOTS IN ABDOMIN
COVID19 VACCINE	JANSSEN	1262566-1	30-39 years	31-60 days	Blood clot in my left forearm. I first noticed it on 4/20 around 7pm. There was a bump (the size of a dime) and small bruise. Overnight the bump got a bit smaller and the bruise expanded. Over the next several days the bump kept diminishing. The bruise remained about the same size and kept getting darker. It's been one week now and the bump is very tiny (size of a small pea), and the bruise is incredibly dark, but showing more of a healing process color.

COVID19 VACCINE	JANSSSEN	1267560-1	50-59 years	31-60 days	This is a 59 year old male that presented to the emergency department at approximately 1447 on 04/27/2021 with sudden onset of left upper and lower extremity weakness and left-sided numbness of his face. The patient stated he may have had some weakness the previous night (04/26/2021), but mostly noticed it when he woke up around 0900 on 04/27/2021. The patient stated he may have also had some transient speech changes which he felt were improved upon emergency department presentation. The patient stated he took an 81 mg aspirin prior to hospital arrival. The patient was overall hemodynamically stable in the emergency department. Past medical history is only significant for benign prostatic hyperplasia. This patient has no history of previous CVA or TIA, no smoking history, no history of clotting disorders, no recent trauma or other injury. CT head revealed a small right frontal subarachnoid hemorrhage with no midline shift and concern for clot. CTA head and neck perfusion study was significant for ?perfusion abnormality involving the right frontal lobe in the region of known subarachnoid hemorrhage, likely related to dural venous sinus thrombosis involving the posterior aspect of the superior sagittal sinus, left greater than right transverse sinus, and left sigmoid sinus.? This patient is noted to have recently received his Johnson and Johnson vaccine on 03/20/2021. The patient was admitted to the intensive care unit. Neurology and hematology were consulted.
COVID19 VACCINE	JANSSSEN	1268363-1	60-64 years	31-60 days	Patient received Johnson Johnson COVID vaccination on March 5th (Its not listed as an option for me to choose - Hence Janssen). Two weeks later patient and wife described symptoms of significant abdominal pain and headache, which improved after 24 hours, since then, abdominal pain on and off with worsening, nausea vomiting and diarrhea. Presented to Hospital with sepsis, negative evaluation, possibly GI etiology, given symptoms. MRI of the abdomen shows left portal vein thrombosis/which is an unusual site. Patient has no liver cirrhosis or metastatic cancer. Is being investigated for idiopathic or acquired thrombophilia
COVID19 VACCINE	JANSSSEN	1270153-1	40-49 years	31-60 days	Left leg start swelling And hurting
COVID19 VACCINE	JANSSSEN	1271081-1	40-49 years	31-60 days	I received the J&J vaccine on 3/16/2021 and then flew to watch over my dads house while he went through cancer treatment. I began to have pain in my chest that was getting progressively worse, yesterday I had a very sharp pain when taking a shallow breath. I went to the hospital they thought I had pneumonia, but then saw a blood dot in right upper side, I've had a prior event but that was attached to an injury in 2012. I've not had any other issues.
COVID19 VACCINE	JANSSSEN	1271151-1	50-59 years	31-60 days	deep venous thrombosis Left leg
COVID19 VACCINE	JANSSSEN	1272064-1	65+ years	31-60 days	left anterior descending coronary artery thrombus requiring thrombectomy, presented as acute anterolateral STEMI
COVID19 VACCINE	JANSSSEN	1272492-1	65+ years	31-60 days	Patient experienced a severe heart attack and was diagnosed with a blood clot
COVID19 VACCINE	JANSSSEN	1273149-1	65+ years	31-60 days	Patient presented to hospital with four days chest pain, dyspnea on exertion and weakness. Work up revealed an acute submassive pulmonary embolism without evidence of deep vein thrombosis in bilateral lower extremities.
COVID19 VACCINE	JANSSSEN	1273426-1	40-49 years	31-60 days	Headache and nausea for 1 week, found to have cavernous sinus thrombosis on MRI 4/29/2021. Started on apixaban
COVID19 VACCINE	JANSSSEN	1273863-1	65+ years	31-60 days	DVT in left popliteal and left superficial femoral vein
COVID19 VACCINE	JANSSSEN	1274213-1	65+ years	31-60 days	DVT and saddle PE. Did have Afib but no A/c
COVID19 VACCINE	JANSSSEN	1277146-1	18-29 years	31-60 days	Patient presented to the emergency department with right-sided pleuritic chest pain-she has a pulmonary embolism on CT angiogram. She was started on heparin and admitted to the medical center. She received her Johnson and Johnson vaccine on 03/04/2021.
COVID19 VACCINE	JANSSSEN	1279509-1	50-59 years	31-60 days	Left lower leg pain and swelling for 1 day. DVT
COVID19 VACCINE	JANSSSEN	1280599-1	65+ years	31-60 days	Deep venous thrombosis
COVID19 VACCINE	JANSSSEN	1281674-1	50-59 years	31-60 days	Large Volume Pulmonary Embolus
COVID19 VACCINE	JANSSSEN	1282638-1	65+ years	31-60 days	Ultrasound done on 4-30-2021 for pain in calf of left leg and numbness of the toes for 7 days. Result came back positive for blood clot.
COVID19 VACCINE	JANSSSEN	1285576-1	65+ years	31-60 days	Shot on 3/8/21 & on 4/23/21 had pain in chest. MWH tested & NOT heart UT LUNGS that a clot in each.
COVID19 VACCINE	MODERNA	0941522-1	50-59 years	31-60 days	I was short of breath and went to emergency room on 1/5/2021. I was diagnosed with bilateral pulmonary embolisms. I was Covid negative and had no other symptoms.

COVID19 VACCINE	MODERNA	0946780-1	30-39 years	31-60 days	#Right parietal/temporal subarachnoid hemorrhage and right intra-axial hemorrhage CT brain (1/12/21): Right parietal intra-axial hemorrhage toward the convexity measuring 2.3 x 1.1 x 1.7 cm with decompression into the subarachnoid space, mild right predominantly temporal and parietal subarachnoid hemorrhage is seen with minimal associated hemorrhage along the tentorium. Mild diffuse right cerebral sulcal effacement with minimal leftward midline shift measuring 2.5 mm. #Dural sinus thrombosis CTA head (1/11/21): Increased density within the superior sagittal sinus, inferior sagittal sinus, and transverse sinuses on noncontrasted images with no flow seen on postcontrast sequences consistent with venous sinus thrombosis #Left sided weakness 2/2 above #Recent jaw alignment procedure
COVID19 VACCINE	MODERNA	0975383-1	65+ years	31-60 days	Acute onset of SOB presented to ED and diagnosed with a pulmonary embolism. Tested positive for SARS-CoV-2 on 01/25/21 using NAT.
COVID19 VACCINE	MODERNA	1073484-1	Unknown	31-60 days	Bilateral pulmonary emboli; A Spontaneous report was received from a consumer concerning a 90-Years-old male patient who received both doses of Moderna's COVID-19 vaccine (mRNA-1273) and experienced Bilateral pulmonary emboli. The patient's medical history was not provided. NO Concomitant medication was reported On 15 Jan 2021, the patient received their first planned doses of mRNA-12 (lot no: 012L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 12 Feb 2021 prior to the onset of the events, the patient received their second planned doses of mRNA-1273 intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 16 Feb 2021, the patient was hospitalized due to Bilateral pulmonary emboli. Treatment for the event included apixaban for blood thinning and Atorvastatin which was stopped a month before was restarted. The action taken with the drug in response to the event is unknown. At the time of this report, the outcome of the event Bilateral pulmonary emboli was considered resolved.; Reporter's Comments: This case concerns a 90-Years-old, male patient who experienced serious event of Bilateral pulmonary emboli. Treatment for the event included apixaban and Atorvastatin (which was stopped a month before) was restarted. Very limited information regarding this event/s has been provided at this time. Further information has been requested.
COVID19 VACCINE	MODERNA	1079224-1	65+ years	31-60 days	3 DAYS AFTER THE 2ND INJECTION, I DEVELOPED 2 BLOOD CLOTS AT THE BASE OF MY LUNGS - 1 ON EACH LUNG. IN CONNECTION WITH THAT, I DEVELOPED SEVER PAIN IN MY LOWER RIGHT FLANK AREA THAT RADIATED TO MY SHOULDER AS WELL AS HIGH BLOOD PRESSURE. THERE IS NO HISTORY IN MY FAMILY OF ANY CLOTTING ISSUES AND I MYSELF HAD NEVER HAD SUCH A THING OCCUR. THE PAIN BECAME SO BAD IT FORCED ME TO GO TO A HOSPITAL EMERGENCY DEPT. AFTER CT SCANS CONFIRMED THE PRESENCE OF THE CLOTS, I WAS SUBSEQUENTLY ADMITTED FOR OBSERVATION ON A REGIMEN OF DRUGS, BLOOD THINNER, PAIN MED, AND A CLOT BUSTER (NOT SURE WHICH MANUFACTURER.) I AM STILL EXPERIENCING PAIN IN MY RIGHT FLANK AREA - SOMEWHAT RADIATING TO MY RIGHT SHOULDER DAY 1 POST DISCHARGE AND AM HAVING TO RELY ON OPIOID PAIN MED AS WELL AS THE CLOT BUSTING MED AND A HIGH BLOOD PRESSURE MED. TO ME, IT SEEMS THAT THIS MAY NOT BE JUST COINCIDENTAL. I WAS FEELING FINE PRIOR TO THE S 2ND DOSE OF THE MODERNA VAC AND THIS SEEMS TO ME THAT IT MIGHT BE RELATED TO THE 2 DOSE.
COVID19 VACCINE	MODERNA	1084499-1	30-39 years	31-60 days	2/22: RLE started to swell, attempted to elevate overnight but no improvement 2/23: 2+ pitting edema in RLE warm to touch 2/24: 2+ pitting edema in RLE warm to touch, painful and SOB 2/24: went to er: dopper on Right leg and CT with contrast of chest 2/24: admitted to hospital for bilateral PE and DVT in RLE
COVID19 VACCINE	MODERNA	1098624-1	40-49 years	31-60 days	Pulmonary embolism diagnosed through CT scan on 2/27/2021. Pain started on 2/23/21.
COVID19 VACCINE	MODERNA	1105198-1	60-64 years	31-60 days	3/4/21 out of breath , peaked 3/08/21. 3/09 pain in right lower leg Hospitalized 4 days - 5 hour procedure for Acute DVT and Acute Saddle pulmonary Embolus
COVID19 VACCINE	MODERNA	1107342-1	65+ years	31-60 days	Blod clot, stroke
COVID19 VACCINE	MODERNA	1109422-1	65+ years	31-60 days	Client received first dose of Moderna vaccine on 1/29/21. Client presented for a second dose on 3/12/21 and reported that he had 'blood clots in the lungs' on 3/7/21 and was hospitalized. The cause of the blood clots is unknown. Client has since recovered and spoke to his doctors and they advised that he receive the second dose of Moderna as scheduled on 3/12/21.

COVID19 VACCINE	MODERNA	1109881-1	40-49 years	31-60 days	<p>two pulmonary embolisms in right lung/Found old pulmonary embolism in left lung; pain moved up bilaterally to her arms, neck and jaw; pain in neck; pain moved up bilaterally to her arms, neck and jaw; wasn't able to ambulate independently; Rib pain; temperature of 101.8; significant decrease in appetite; unusual pain in her legs, hips and lower back; A spontaneous report was received from a nurse concerning a 46-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced unusual pain in her legs, hips, lower back, pain in both arms, neck jaw and ribs, decrease in appetite, fever, and pulmonary embolism. The patient's medical history was not provided. Concomitant medications included levothyroxine, prednisone, tizanidine and apixaban. On 30-Dec-2020, prior to the onset of events, the patient received their first of two planned doses of mRNA-1273 (lot/batch 011J20A) intramuscularly for prophylaxis of COVID-19 infection and patient had a sore arm, muscle aches and slight headaches. On 25-Jan-2021, prior to the onset of events, the patient received their second of two planned doses of mRNA-1273 (lot/batch 026L20A) intramuscularly for prophylaxis of COVID-19 infection. On 03-Feb-2021 the patient started developing an unusual pain in her legs, hips, and lower back that eventually moved up to her arms, neck and jaw. She reported that she had a significant decrease in appetite that Saturday, 06-Feb-2021, and on 07-Feb-2021, she had a temperature of 101.8. She reported feeling like she had the flu. Patient reported having a COVID-19 test that came back negative. The pain continued to increase between Sunday night and Tuesday morning. Patient then developed pain in her ribs when she would lay down. She wasn't able to ambulate independently. On 09-Feb-2021, she went to the hospital. They did a chest X-ray and computed tomography (CT) scan. Those tests showed two new pulmonary embolisms in the right lung and an old pulmonary embolism in the left lung. Patient was hospitalized 09-Feb-2021 until 12-Feb-2021. She reported that her body was still inflamed. In her labs it showed her thyroid levels had doubled from her previously good thyroid levels checked in Oct 2020. Treatment information was not provided. The patient received both scheduled doses of mRNA-1273; therefore, action taken with mRNA-1273 in response to the events was not applicable. The outcomes of the events, pain in her legs, hips, lower back, neck, jaw bilateral arm pain, decrease in appetite, fever, pain in ribs and pulmonary embolism, were considered controlled with medication.;</p> <p>Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p>
COVID19 VACCINE	MODERNA	1110612-1	40-49 years	31-60 days	<p>EDC: 25 APR 2021 AE1: Superficial Venous Thrombosis: On 10 Feb 2021, patient presents with RLL pain and swelling. Dopplers with non-occlusive Superficial Venous Thrombosis. Started on 40 Lovenox qd. On 23 Feb, had worsening pain and repeat doppler showed occlusive SVT. Her Lovenox was increased to 40 mg BID and referred to Hematology. Her hematologist increased her lovenox to 80 mg bid. SAE: Pulmonary Embolism: On 3/9 patient developed Shortness of breath and chest pain and went to ED where she was diagnosed with Bilateral pulmonary emboli. She was admitted to the hospital and started on an heparin drip. AE2: SVT: Patient developed a second SVT after discharge from hospital on 17 Mar 2021 that is located away from original SVT site.</p>

COVID19 VACCINE	MODERNA	1114275-1	65+ years	31-60 days	<p>Difficulty breathing; Chest pains; Blood clots in both of her lungs; Blood clots in both legs; Tired/ wiped out; A spontaneous report was received from a consumer (patient's daughter), concerning a 75-years-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced difficulty breathing (dyspnoea), chest pains, blood clots in both of her lungs (pulmonary embolism), blood clots in both legs (deep vein thrombosis), tired/ wiped out (fatigue). No medical history was reported. No concomitant medications were reported. On 03 Feb 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: not provided). On 03 Mar 2021, the patient received their second of two planned doses of mRNA-1273 (Lot number: not provided) intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, the patient was completely wiped out for a couple of days following the vaccine. She was very tired and out of it. On an unknown date, over the weekend, the patient had difficulty breathing. On 08 Mar 2021, in the morning, the patient was hospitalized for chest pains and difficulty breathing. On the same day lab data revealed that she had blood clots in both of her lungs. On an unknown date, the patient had clots in both legs as well. She was hospitalized for a week and was in rehabilitation being monitored. The reporter also informed that the patient will be hospitalized until 18 Mar 2021 for the clots in both legs. The patient received both scheduled doses of mRNA-1273 prior to the event, therefore action taken with the drug in response to the event is not applicable. The outcome of the events of difficulty breathing (dyspnoea), chest pains, blood clots in both of her lungs (pulmonary embolism), blood clots in both legs (deep vein thrombosis), tired/ wiped out (fatigue) was unknown. The reporter did not provide assessment for the events of difficulty breathing (dyspnoea), chest pains, blood clots in both of her lungs (pulmonary embolism), blood clots in both legs (deep vein thrombosis), tired/ wiped out (fatigue). Follow-up received on 16 Mar 2021 included hospitalization end date, date of first dose of vaccine.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p>
COVID19 VACCINE	MODERNA	1118504-1	65+ years	31-60 days	<p>Pt received dose 2 of Moderna COVID19 vaccine on 2/12. Admitted to the hospital 2/24/21 with acute ITP. Subsequently admitted 3/19 with extensive bilateral LE DVTs and pulmonary embolism.</p>
COVID19 VACCINE	MODERNA	1118754-1	50-59 years	31-60 days	<p>Patient started to have symptoms of progressive shortness of breath two weeks after the 1st vaccine shot and she presents to the hospital on 3/18 and was found to have submissive PE</p>
COVID19 VACCINE	MODERNA	1119815-1	65+ years	31-60 days	<p>Feeling terrible; Feeling tired; Blood clot in knee; A spontaneous report was received from a nurse who was a 72-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and developed a blood clot in her knee, feeling terrible and feeling tired.. The patient's medical history was not provided by the reporter. No relevant concomitant medications were reported. On 25 Feb 2021, the patient received her second of two planned doses of mRNA-1273 (Lot number: 031M20A) intramuscularly for prophylaxis of COVID-19 infection. On 04 Mar 2021, a week after vaccination, the patient was seen at the hospital and was diagnosed with a blood clot in her knee of unknown origin. She also reported that she has continued feeling terrible and feeling tired. Lab details were not provided by the reporter. Treatment for the events were unknown. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, blood clot in her knee, feeling terrible and feeling tired, were considered unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

COVID19 VACCINE	MODERNA	1126059-1	65+ years	31-60 days	Bilateral pulmonary emboli; A spontaneous report was received from a physician concerning an 80-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) experienced shortness of breath and oxygen level low. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. The patient received her first of two planned doses of mRNA-1273 (LOT: unknown) on 05-Feb-2021. On 05-Mar-2021, approximately 1 day prior to the onset of the symptoms, the patient received their second of two planned doses of mRNA-1273 (Batch number: 048A21A) intramuscularly for prophylaxis of COVID-19 infection. On 06-Mar-2021, the patient developed shortness of breath and her oxygen level was low. On 09-Mar-2021, she was diagnosed with bilateral pulmonary embolisms. No hospitalization was required. The reporter stated that the patient had no history of blood clots. Treatment for the event included apixaban. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the drug in response to the events is not applicable. The outcome of the events was considered unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded
COVID19 VACCINE	MODERNA	1129682-1	Unknown	31-60 days	a blood clot in his leg behind his knee; blood clots on both of his lungs; leg pain and cramps that got worst as time went by; A spontaneous report was received from a consumer concerning a 65 year old male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced leg pain and cramps that worsen as time progressed, a blood clot in his leg behind his knee, and blood clots in both lungs. The patient's medical history include high blood pressure. The relevant concomitant medications are Lisinopril, Paroxetine, and Multivitamins. On 31 Dec 2020, the patient received the first of two planned doses of mRNA-1273 (lot/batch: 026120a) intramuscularly for prophylaxis of COVID-19 infection. On 28 Jan 2021, prior to the onset of the events, the patient received the second of two planned doses of mRNA-1273 (lot/batch: 004m20a) via unknown route in left arm for prophylaxis of COVID-19 infection. On 01 Mar 2021, the patient experienced leg pain and cramps that worsen with time. 03 Mar 2021, the patient developed a blood clot in his leg behind his knee and blood clots on both lungs. The seriousness criteria for the events, blood clot in the leg behind the knee and blood clots in both lungs was were life threatening and medically significant. The Laboratory findings include an ultrasound showing a blood clot in the leg behind the knee on 03 Mar 2021. On unknown day of Mar 2021, chest CT showed blood clots in both lungs. Treatment medication included rivaroxaban prescribed earlier by his physician. Action taken with mRNA-1273 in response to the events was not applicable. At the time of this report, the outcome of the events, leg pain and cramps that got worst as time went by and a blood clot in his leg behind his knee was unknown. The event, blood clots on both of his lungs was considered recovering on an unknown date.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1139202-1	65+ years	31-60 days	02/20/2021Shortness of breath on climbing 15-20 stairs, 02/24/2021/D-dimer test very high, 02/24/2021Admitted to hospital. CT Angiogram showed blood clots in lungs. Administered IV Hyperin. scans of legs-no blood clots, Scan of heart and arteries. 02/26/2021Released with perscription of Eliquis. 03/04/21 Blood test by Hematologist Normal; 03/08/21 CT Scan of body-Normal-no tumors/cancer detected
COVID19 VACCINE	MODERNA	1144027-1	60-64 years	31-60 days	Please note: The vaccination record I received with lot number is very difficult to read!!! My first vaccination was 12/31/20 and lot number written down but hard to read is (U37K20A but could be V37K20A) The second shot was 1/27/21 and lot number written down could be (04120A, or could read O9120A!) I had symptoms of a Pulmonary embolism while cross country skiing March 18 and officially diagnosed with PE on March 22, 2021. I was tested for Covid 19 on March 23, 2021 with negative results. I had been reporting my side effects (which were none) for the previous 6 weeks following the second vaccination. I did have cramping like feeling in my right calf following a x-country ski weekend about 4 weeks prior to the actual PE (2/22/21) but it appeared to resolve after about 7-10 days

COVID19 VACCINE	MODERNA	1147138-1	60-64 years	31-60 days	<p>Very hard to breath for few minutes; Swollen arm; Nausea; Headaches; Blood clogging; A spontaneous report was received from a consumer concerning a 63 years old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events very hard to breath for few minutes/dyspnoea, blood clogging/thrombosis, headaches, nausea, swollen arm/peripheral swelling. The patient's medical history included high blood pressure. Concomitant product use was not provided by the reporter. On 15 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (lot: 027L20A) for prophylaxis of COVID-19 infection. On 08 Feb 2021, the patient received their second of two planned doses of mRNA-1273 (lot: 0101M20A) for prophylaxis of COVID-19 infection. The first dose of vaccine was taken in non dominant arm and second dose was taken in right dominant arm. On an unknown date, the patient experienced swollen arm. In between the two doses she felt very hard to breath for few minutes and when she took a deep breath it was fine. She had tylenol for the headaches after the second dose on 08 February 2021. She also had nausea along with headaches. She had blood clogging when she was in a blood donation camp. The event very hard to breath for few minutes and blood clogging were considered as medically significant. Thiamine was provided as medication The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the drug in response to the events is not applicable. Follow-up received on 17 Mar 2021 included updated date for first dose of vaccine, and the events very hard to breath for few minutes/dyspnoea, blood clogging/thrombosis.; Reporter's Comments: Based on the current available information which shows a strong temporal association between the use of the mRNA-1273 and the reported events and excluding all other etiology, a causal relationship cannot be excluded. Nausea and headache are consistent with the safety profile of the product</p>
COVID19 VACCINE	MODERNA	1151065-1	65+ years	31-60 days	<p>Stroke; Blood clot on the brain; I Just sort of zoned out on them; Arm soreness; I Just kept getting tireder; A spontaneous report was received from a consumer, concerning a 69-years old male patient, who received Moderna's COVID-19 vaccine and experienced stroke, blood clot on brain, arm soreness without redness and swelling, he just kept getting tireder, he just sort of zoned out on them. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On 05 Jan 2021, prior to the onset of events, the patient received the first of two planned doses of mRNA-1273 (lot number 037K20A) via unknown route for COVID-19 infection prophylaxis. On 05-FEB-2021, prior to the onset of events, the patient received the second of two planned doses of mRNA-1273 (lot number 032L20A) via unknown route for COVID-19 infection prophylaxis. On 05 Feb 2021, after the second dose of vaccine, the patient experienced arm soreness and fatigue, He did not get any medication or treatments for his arm soreness without redness and swelling and and just kept getting tireder events. On10-MAR-2021 patient experienced just sort of zoned out of them, stroke, blood clot on brain. An ambulance was called for him and he was taken to the hospital where he received MRIs, and CT scans. He states they think it was a stroke. No treatment medication was reported. Action taken with mRNA-1273 in response to the event was not applicable. The outcome of the events (arm soreness without redness and swelling and he was just kept getting tireder) was recovered but the events (stroke, blood clot on brain, he just sort of zoned out on them) not resolved at the time of this report.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>
COVID19 VACCINE	MODERNA	1157590-1	Unknown	31-60 days	<p>Blood clots in his lungs (After second dose); A spontaneous report was received from consumer, concerning himself, a 71-year -old elderly, male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced blood clots in lungs (Pulmonary embolism). The patient's medical history was reported as unknown. Concomitants reported included Metoprolol, Tamsulosin, Gabapentin, Metformin, Fenofibrate and Losartan for unknown indication. On 8 Mar 2021 patient received second of two planned doses of mRNA-1273 (Lot number: 040A21A) via unknown route for prophylaxis of COVID-19 infection. On 18 Mar 2021 patient went to doctor and after some studies that included a CT scan they discovered he had blood clots in his lungs. The event blood clots in lungs (Pulmonary embolism) was medically significant. It was reported that, he was prescribed with a blood thinner for treatment purpose. Action taken with mRNA-1273 in response to the event was not applicable. The outcome of the event, blood clots in lungs was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p>

COVID19 VACCINE	MODERNA	1157608-1	65+ years	31-60 days	Stroke; Blood clots in his brain; Limited motion on the left side of the face and arm; Turned my life upside down; A spontaneous report was received from a consumer concerning a 73 -year-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and reported events blood clots in brain/ cerebral thrombosis, stroke/ cerebrovascular accident, turned life upside down/loss of personal independence in daily activities and limited motion on the left side of the face and arm/mobility decreased. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. The patient received the first of the two planned doses of mRNA-1273 (lot/batch number: 04112A) on 08 Jan 2021. On 05 Feb 2021, prior to the onset of the events, the patient received their second of the two planned doses of mRNA-1273(lot/batch: 01020A) via unknown route in the left arm for prophylaxis of COVID-19 infection. On 26 Feb 2021, the patient experienced blood clots in brain, stroke and he patient woke up in the morning with limited motion on the left side and was subsequently hospitalized for two days. The patient's life upside down. Treatment information included blood thinners, small dose of acetyl salicylic acid, rosuvastatin, CoQ and Vitamin D3. The patient received both scheduled doses of mRNA-1273 prior to the events therefore, action taken with the drug in response to the events was not applicable. The outcome of the events blood clots in brain, stroke, turned life upside down and limited motion on the left side of the face was not reported.; Reporter's Comments: This case concerns a 73 -year-old, male patient, who reported cerebral thrombosis, stroke, loss of personal independence, and mobility decreased. Very limited information regarding these events has been provided at this time. Further information has been requested.
COVID19 VACCINE	MODERNA	1171786-1	50-59 years	31-60 days	VTE- PE and DVT dx on 4/5/21
COVID19 VACCINE	MODERNA	1173925-1	65+ years	31-60 days	Shortness of breath, cough onset Sunday April 4th. DATE OF SERVICE: 04.06.2021 CT ANGIOGRAPHY, CHEST (CPT=71275); PULMONARY EMBOLUS PROTOCOL; 3-D RECONSTRUCTION CLINICAL INDICATION: SOB (shortness of breath) COMPARISON STUDY: 10/9/2020 TECHNIQUE: Axial images of the chest were performed during dynamic contrast enhancement for the optimization of the opacification of the pulmonary arteries, following IV administration of 80 mL of Isovue 370. Three-dimensional reformation into the coronal plane was performed. Automated exposure control and ALARA manual techniques for patient specific dose reduction were followed while maintaining the necessary diagnostic image quality. ADVERSE REACTION: None FINDINGS: PULMONARY ARTERIES: There is a large filling defect within the right interlobar artery, extending into the lobar, segmental, and subsegmental branches of the right lower lobe. There is expansion of the right interlobar artery by this thrombus. Small filling defect is noted within the distal left main pulmonary artery, with some extension to the left upper lobe and left lower lobe lobar segments. HEART AND VASCULATURE: The heart is normal size. No pericardial effusion. There is no evidence of right heart strain. MEDIASTINUM AND HILA: There is no mediastinal or hilar lymphadenopathy. LUNGS AND AIRWAYS: Heterogeneous densities are seen in the right lower lobe, new since the prior exam. Scarring is noted in the superior segment of the right lower lobe as well as in the anterior left lower lobe.. PLEURA: Small right pleural effusion. CHEST WALL, LOWER NECK, AND AXILLA: Grossly unremarkable. UPPER ABDOMEN: Grossly unremarkable. OSSEOUS STRUCTURES: Degenerative changes are seen within the visualized spine. IMPRESSION 1. Bilateral PE, with extensive thrombus on the right and minimal thrombus on the left as detailed above. 2. Small right pleural effusion and heterogeneous right lower lobe consolidation, likely reflecting pulmonary infarction.
COVID19 VACCINE	MODERNA	1174168-1	18-29 years	31-60 days	Right lower lobe Pulmonary Embolism diagnosed in the ER after presenting with severe right sided flank pain and shortness of breath,
COVID19 VACCINE	MODERNA	1177218-1	50-59 years	31-60 days	Right lower extremity deep venous thrombosis in popliteal and femoral veins, swollen discolored leg
COVID19 VACCINE	MODERNA	1184699-1	30-39 years	31-60 days	Heart attack (blood clot in major artery) approximately 6 weeks post 2nd Moderna dose. Surgery done in cath lab to address blockage. Released from hospital several days later.
COVID19 VACCINE	MODERNA	1187863-1	65+ years	31-60 days	DVT right leg. Total obstruction of Popiteal vein, as well as anterior and posterior tibial veins. Subsequent Pulmonary emboli to both lungs. Symptoms started about a week following 1st vaccine. The symptoms got worse following the 2nd COVID vaccine, and required an ER visit.

COVID19 VACCINE	MODERNA	1189624-1	65+ years	31-60 days	Pulmonary embolism; This spontaneous case was reported by a physician (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Pulmonary embolism) in a 67-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included No adverse event (No reported medical history). In March 2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Apr-2021, the patient experienced PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criteria hospitalization prolonged and life threatening). The patient was hospitalized on sometime in April 2021 due to PULMONARY EMBOLISM. At the time of the report, PULMONARY EMBOLISM (Pulmonary embolism) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Treatment information was not provided. This case refers to a 67 year-old elderly female patient who developed pulmonary embolism about two weeks after receiving the second dose of mRNA-1273 vaccine. Very limited information has been provided at this time.; Sender's Comments: This case refers to a 67 year-old elderly female patient who developed pulmonary embolism about two weeks after receiving the second dose of mRNA-1273 vaccine. Very limited information has been provided at this time.
COVID19 VACCINE	MODERNA	1192464-1	65+ years	31-60 days	Fatigue, achy all over, pain under right rib cage that hurt threw to my back. Went to med center and was seen by Dr. He was concerned so that he insisted that I go to the hospital to be admitted on Tuesday 4/6/21. Was admitted and blood work was done and ct abdomen and car which was negative. More lab work was done on 4/7/21 which showed a elevated d-dimer. At that time a ultrasound of legs done which showed a clot in my right leg. Then a ct chest was scheduled and done 4/8/21 which showed a clot in my right lung.
COVID19 VACCINE	MODERNA	1196583-1	40-49 years	31-60 days	Have had tiredness since 2nd vaccine in February and noticed shortness of breath when walking or going up stairs in mid March. Around 4/1, I started having left rib pain preventing me from sleeping on my left side and then could not breath during a massage on 4/8. On April 9th, I was diagnosed with multiple pulmonary embolisms (clots) in both lungs, reducing my lung capacity to only 30% of normal. This could be due to Loestrin birth control but I have taken hormones in the past for IVF and when younger for birth control. The reaction may be due to a combination of vaccine, Loestrin and iron but triggered by vaccine. I am currently on Eliquis to treat pulmonary embolisms.
COVID19 VACCINE	MODERNA	1200562-1	30-39 years	31-60 days	3/14/21 - took a dose of miralax, 30 minutes later became flushed, diaphoretic, developed a red/itchy rash on my head/neck/back/arms, 10 minutes later I had diarrhea, 10 minutes later intractable vomiting, EMS was called, BP 70/30 in ambulance, received 2L NS IVF and 60 mEq potassium (K 2.8 in ED), stayed in ED for 8 hours until BP 110s/70s. 3/19/21 - diagnosed with right occlusive thrombus in superficial cephalic vein large enough it was characterized as a DVT, started on therapeutic Eliquis. 3/22/21 - diagnosed with left occlusive thrombus in main branch of cephalic vein. Had to be out of work for 4 weeks until I was cleared by vascular surgery and hematology to return.
COVID19 VACCINE	MODERNA	1202241-1	65+ years	31-60 days	nonocclusive deep vein thrombosis (extending from upper femoral vein to Popliteal vein in left leg,, ) pulmonary embolism affected left pulmonary lobe) - no heart damage or pulmonary infarct; Was hospitalized at Hospital on Saturday 4/10 and discharge is scheduled for 4/13.
COVID19 VACCINE	MODERNA	1203350-1	30-39 years	31-60 days	Severe headaches began 3/19/21; Urgent Care treated with meds and did CT Scan; sent to ER on 3/25/21. Admitted to hospital. MRI and CT scans done; Lumbar Puncture done--no bacteria; diagnosed as Cerebral Vascular Sinus Thrombosis; treated with Lovonox for 5 days then switched to Pradaxa when released from hospital; given oxycodon, dilaudid, and tylenol for pain. Starting 4/1/21, numbness in right arm down to fingers. Sent to ER again on 4/8/21 as headaches and numbness worsened. MRI and CT done. Clot dissolving but pain continued at 10/10 level. Released and continues on Oxycodon, Tylenol, Elavil, without relief as of today, 4/13/21. Still incapacitated by pain and unable to walk at length, work, or any normal activities.
COVID19 VACCINE	MODERNA	1204823-1	18-29 years	31-60 days	I had 2 blood clots on my vertebral arteries that caused me to have a stroke. This happened on March 22nd which is 2 months after receiving my 2nd dose of Moderna. I am still going through the recovery process.
COVID19 VACCINE	MODERNA	1208047-1	65+ years	31-60 days	Pulmonary Embolism on 3-11-2021

COVID19 VACCINE	MODERNA	1208402-1	65+ years	31-60 days	Patient presented to ED ~2months after 2nd Moderna vaccine with multiple subsegmental PEs as well as small popliteal and calf vein thrombosis. Admitted for 2 days for anticoagulation then sent home on oral anticoagulation in stable condition. No history of thrombosis.
COVID19 VACCINE	MODERNA	1208418-1	40-49 years	31-60 days	Pulmonary embolism diagnosed following CT scan on 4/9/2021. Noticed pain in right lung a few days previous (4/7/2021). Prescribed Xarelto.
COVID19 VACCINE	MODERNA	1212394-1	60-64 years	31-60 days	Day after the shot (March 3) he started having shortness of breath and then continued up until March 16 started running fever of 102.9 and still having difficulty breathing-went to ER and then diagnosed with blood clots in lung ""acute pulmonary emboli"" and pulmonary infarct and his heart was enlarged-by CAT scan. In ICU for 3 days and discharged at that time out of ICU to home.""
COVID19 VACCINE	MODERNA	1212599-1	65+ years	31-60 days	Blood clot resulting in stroke in left brain
COVID19 VACCINE	MODERNA	1212657-1	65+ years	31-60 days	4/1/21 Patient developed breathlessness, it progressed until she presented to local ER 4/13 with hypoxemia, tachycardia due to Submassive pulmonary emboli, also found to have R pulmonary infarct and asymptomatic DVTs in R femoral and popliteal, L popliteal veins. Patient was admitted to hospital, treated with IV UFH, doing well. Anticipate discharge in 1-2 days. Note hospitalization data below is tentative as pt is still in hospital
COVID19 VACCINE	MODERNA	1215851-1	65+ years	31-60 days	deep vein thrombosis pulmonary embolism
COVID19 VACCINE	MODERNA	1216642-1	30-39 years	31-60 days	In the 3 weeks leading up to February 10th, I became progressively more bloated with fluid in my stomach area, with an increasing feeling of fullness. By the 10th, I felt so full that I had only eaten one meal in two days. I had also been sleeping upright for days to attempt to clear what I perceived to be a stomach blockage and therefore was quite tired. I walked in to the ER and the x-ray revealed the blood clot in my portal vein. The physician immediately had enoxaparin administered to me and I was admitted. I received another enoxaparin dose the next morning. I was discharged on Xarelto 15mg twice a day in the afternoon of Feb 11th. I am continuing on Xarelto as my hematologist runs various tests and I have an EGD on 4/16 due to a possible stomach ulcer. I was diagnosed with: Mesenteric venous thrombosis Elevated transaminase measurement Fatty liver
COVID19 VACCINE	MODERNA	1219035-1	50-59 years	31-60 days	Submassive Pulmonary Embolism
COVID19 VACCINE	MODERNA	1220899-1	Unknown	31-60 days	blood clots in both legs; severe pain in both his legs; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (blood clots in both legs) in a 67-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 008D21A and 011A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history was reported.). On 25-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 01-Apr-2021, the patient experienced THROMBOSIS (blood clots in both legs) (seriousness criterion medically significant) and PAIN IN EXTREMITY (severe pain in both his legs). At the time of the report, THROMBOSIS (blood clots in both legs) and PAIN IN EXTREMITY (severe pain in both his legs) outcome was unknown. Not Provided For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided. Treatment included Eliquis (apixaban) for three months. Reportedly, the patient was put on apixaban 2 tablets every morning and evening for 14 days and will then take 1 tablet every morning and evening for a total of 3 months. He does think that the medicine is helping. Patient stated that he never had blood clots before and suspects that it was from the shot.; Sender's Comments: Very limited information has been provided at this time. Further information has been requested. Based on the current information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded

COVID19 VACCINE	MODERNA	1220980-1	65+ years	31-60 days	<p>Blood clot; Left leg pain; Discoloration (blue-purple); Swelling; This spontaneous case was reported by an other health care professional and describes the occurrence of THROMBOSIS (Blood clot), PAIN IN EXTREMITY (Left leg pain), SKIN DISCOLOURATION (Discoloration (blue-purple)) and SWELLING (Swelling) in a 78-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 011J20A and 013L20A) for COVID-19 vaccination. The patient's past medical history included Clot blood in 2010. Concurrent medical conditions included Drug allergy (Dalaudid, Ambien and Demerol) and Hypertension. Concomitant products included DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE (FARXIGA), GLIMEPIRIDE (AMARYL), ACETYLCARNITINE HYDROCHLORIDE (NEUROTIN [ACETYLCARNITINE HYDROCHLORIDE]), COLECALCIFEROL (CALTRATE VITAMIN D DAILY), MINERALS NOS, VITAMINS NOS (CENTRUM A TO ZINC) and VITAMIN D NOS for an unknown indication. On 11-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Mar-2021, the patient experienced PAIN IN EXTREMITY (Left leg pain) (seriousness criterion hospitalization), SKIN DISCOLOURATION (Discoloration (blue-purple)) (seriousness criterion hospitalization) and SWELLING (Swelling) (seriousness criterion hospitalization). On an unknown date, the patient experienced THROMBOSIS (Blood clot) (seriousness criterion hospitalization). At the time of the report, THROMBOSIS (Blood clot), PAIN IN EXTREMITY (Left leg pain), SKIN DISCOLOURATION (Discoloration (blue-purple)) and SWELLING (Swelling) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Patient was sent to hospital to remove clots. The patient stated that the clot was 2/3 size of thigh. The patient scheduled to have a second procedure in May to remove blockages from iliac. Action taken with mRNA-1273 was not applicable. Based on the current available information and temporal association between the use of the product and the onset date of the reported events, a causal relationship cannot be excluded. Prior medical history of blood clot is considered a significant risk factor.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the reported events, a causal relationship cannot be excluded. Prior medical history of blood clot is considered a significant risk factor.</p>
COVID19 VACCINE	MODERNA	1230972-1	65+ years	31-60 days	<p>Blood Clot in the Left leg; Pain in the Left Leg; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (Blood Clot in the Left leg) in a 74-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 007B21A and 007B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Blood pressure high. Concomitant products included LISINAPRIL and HCTZ for Blood pressure high. On 27-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 2 dosage form. On 13-Apr-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced PAIN IN EXTREMITY (Pain in the Left Leg). On 14-Apr-2021, the patient experienced THROMBOSIS (Blood Clot in the Left leg) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Blood Clot in the Left leg) and PAIN IN EXTREMITY (Pain in the Left Leg) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Apr-2021, Ultrasound joint: ultrasound (abnormal) Blood Clot in the Left leg. Patient did not have a history of Blood Clots. She was Not taking any hormones (Estrogen, Progesterone) Treatment for event included Eliquis for blood clot. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the drug in response to the events is not applicable. Based on the current available information and temporal association between the use of the product and the onset date of the reported event a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the reported event a causal relationship cannot be excluded.</p>

COVID19 VACCINE	MODERNA	1235521-1	65+ years	31-60 days	<p>After the vaccination, and while in the hospital, she was diagnosed with a blood clot in the left atrium the size of a golf ball; Reported she was diagnosed with a spontaneous peptic ulcer bleed; Stated that she feels like she is ""sitting on a powder keg""; This spontaneous case was reported by a patient (subsequently medically confirmed) and describes the occurrence of ATRIAL THROMBOSIS (After the vaccination, and while in the hospital, she was diagnosed with a blood clot in the left atrium the size of a golf ball) and PEPTIC ULCER HAEMORRHAGE (Reported she was diagnosed with a spontaneous peptic ulcer bleed) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 022M20A and 211M28-9) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Heart failure (7 years ago- consumer reported it resolved on its own but was placed on Entresto at that time) in 2014 and Arterial stent insertion (Left atrial appendage closure device to treat atrial fibrillation and prevent clots) in 2019. Concurrent medical conditions included Arthritis, Cardiac disorder NOS (Body aches), Headache, Fluid imbalance (Fluid in feet), High cholesterol, Hypotension and Pain. Concomitant products included CARVEDILOL (COREG), HCTZ, VITAMIN C [ASCORBIC ACID], ATORVASTATIN CALCIUM (LIPITOR), ACETYLSALICYLIC ACID (BABY ASPIRIN) and PARACETAMOL (TYLENOL) for an unknown indication. On 03-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 24-Mar-2021, the patient experienced ATRIAL THROMBOSIS (After the vaccination, and while in the hospital, she was diagnosed with a blood clot in the left atrium the size of a golf ball) (seriousness criteria hospitalization prolonged and medically significant). On an unknown date, the patient experienced PEPTIC ULCER HAEMORRHAGE (Reported she was diagnosed with a spontaneous peptic ulcer bleed) (seriousness criterion medically significant) and FEELING ABNORMAL (Stated that she feels like she is ""sitting on a powder keg""). The patient was hospitalized from 24-Feb-2021 to 12-Mar-2021 due to ATRIAL THROMBOSIS. At the time of the report, ATRIAL THROMBOSIS (After the vaccination, and while in the hospital, she was diagnosed with a blood clot in the left atrium the size of a golf ball), PEPTIC ULCER HAEMORRHAGE (Reported she was diagnosed with a spontaneous peptic ulcer bleed) and FEELING ABNORMAL (Stated that she feels like she is ""sitting on a powder keg"" outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 06-Feb-2021, Echocardiogram: results are not mentioned (Inconclusive) Results are not mentioned. The patient stated that she initially was being cared for by a small, local hospital but was transferred to a larger hospital. The patient reported that she has never had any blood clots until now. Treatment for the event included apixaban (twice daily). The patient received both scheduled doses of mRNA-1273 prior to the event; therefore, action taken with the drug in response to the event is not applicable. This case was linked to MOD-2021-075865 (Patient Link).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.""</p>
COVID19 VACCINE	MODERNA	1245403-1	65+ years	31-60 days	<p>Pulmonary Embolism; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Pulmonary Embolism) in a 68-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included No adverse event (No medical history reported). On 21-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 28-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 2 dosage form. On 07-Mar-2021, the patient experienced PULMONARY EMBOLISM (Pulmonary Embolism) (seriousness criterion hospitalization). The patient was hospitalized on 07-Mar-2021 due to PULMONARY EMBOLISM. At the time of the report, PULMONARY EMBOLISM (Pulmonary Embolism) outcome was unknown. Not Provided Patient was prescribed Xarelto. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, Very limited information regarding this event/s has been provided at this time. Further information has been requested.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, Very limited information regarding this event/s has been provided at this time. Further information has been requested.</p>

COVID19 VACCINE	MODERNA	1245413-1	Unknown	31-60 days	<p>Blood clot in left leg and moved down to bottom of her heal; Hard Time Walking due to blood clot; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (Blood clot in left leg and moved down to bottom of her heal) in a 59-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history was provided.). Concomitant products included ACETYLSALICYLIC ACID (ASPIRIN 81) for an unknown indication. On 26-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 26-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 02-Apr-2021, the patient experienced THROMBOSIS (Blood clot in left leg and moved down to bottom of her heal) (seriousness criterion medically significant) and GAIT DISTURBANCE (Hard Time Walking due to blood clot). At the time of the report, THROMBOSIS (Blood clot in left leg and moved down to bottom of her heal) and GAIT DISTURBANCE (Hard Time Walking due to blood clot) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Patient reported that doctor prescribed prednisone to treat the symptoms. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>
COVID19 VACCINE	MODERNA	1245438-1	65+ years	31-60 days	<p>Pulmonary embolism; Nausea; Vomiting; Chest pain/right upper quadratic thoracic pain; Feeling unwell; This spontaneous case was reported by a patient family member or friend and describes the occurrence of PULMONARY EMBOLISM (Pulmonary embolism) in an 85-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 012A21A and 016M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 09-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 14-Mar-2021, the patient experienced MALAISE (Feeling unwell). On 15-Mar-2021, the patient experienced CHEST PAIN (Chest pain/right upper quadratic thoracic pain). On 15-Apr-2021, the patient experienced PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criterion hospitalization), NAUSEA (Nausea) and VOMITING (Vomiting). The patient was hospitalized on 15-Apr-2021 due to PULMONARY EMBOLISM. At the time of the report, PULMONARY EMBOLISM (Pulmonary embolism), CHEST PAIN (Chest pain/right upper quadratic thoracic pain), MALAISE (Feeling unwell), NAUSEA (Nausea) and VOMITING (Vomiting) outcome was unknown. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Mar-2021, SARS-CoV-2 test: negative (Negative) Negative. On 17 Mar 2021 the patient had an x-ray and EKG performed because she was not feeling well and had chest pain- no results provided. On15 Apr 2021 the patient went to emergency room and was hospitalized for multiple pulmonary embolisms with parts being infarcted. No treatment information was provided. No relevant concomitant medications were reported. Company Comment - Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

COVID19 VACCINE	MODERNA	1245443-1	65+ years	31-60 days	<p>extremely high blood pressure; severe headache; DVT to right leg starting at the groin and going down to the foot; worsen edema with 4+and 5+ pitting edema in right leg; This spontaneous case was reported by a nurse (subsequently medically confirmed) and describes the occurrence of DEEP VEIN THROMBOSIS (DVT to right leg starting at the groin and going down to the foot) in a 67-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 031B21A and 030A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history was provided.). Concomitant products included DUPILUMAB (DUPIXENT) from 09-Mar-2021 to 06-Apr-2021 and DULOXETINE HYDROCHLORIDE (CYMBALTA) for an unknown indication. On 11-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 08-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 14-Apr-2021, the patient experienced DEEP VEIN THROMBOSIS (DVT to right leg starting at the groin and going down to the foot) (seriousness criterion medically significant) and OEDEMA PERIPHERAL (worsen edema with 4+and 5+ pitting edema in right leg). On an unknown date, the patient experienced HYPERTENSION (extremely high blood pressure) and HEADACHE (severe headache). At the time of the report, DEEP VEIN THROMBOSIS (DVT to right leg starting at the groin and going down to the foot), OEDEMA PERIPHERAL (worsen edema with 4+and 5+ pitting edema in right leg), HYPERTENSION (extremely high blood pressure) and HEADACHE (severe headache) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Apr-2021, Ultrasound Doppler abnormal: abnormal (abnormal) Causative extensive occlusive thrombus"", DVT in the right leg starting from the groin going down to the foot. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient had an ultrasound of the leg performed. The diagnosis showed ""causative extensive occlusive thrombus"". Patient reported taking heparin and acetaminophen(Tylenol) ad treatment for the symptoms. This case was linked to (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. MOD-2021-079102:1st dose""</p>
COVID19 VACCINE	MODERNA	1248086-1	40-49 years	31-60 days	<p>Moderna COVID-19 Vaccine EUA: patient underwent L1-2 corpectomy, pedicle subtraction osteotomy, and extension of fusion from T4 to the pelvis two months after vaccination. During surgery patient became thrombocytopenic and required massive transfusion. Thirteen days after surgery found to have bilateral pulmonary embolisms and deep vein thromboses and placed on anticoagulation. Patient subsequently suffered cardiac arrest and was unable to be resuscitated.</p>
COVID19 VACCINE	MODERNA	1249658-1	30-39 years	31-60 days	<p>blood clot in left leg; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of VENOUS THROMBOSIS LIMB (blood clot in left leg) in a 36-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 013L20A and 013L20A) for COVID-19 vaccination. The patient's past medical history included No adverse event (No medical history reported.). Concomitant products included ASPIRIN [ACETYLSALICYLIC ACID] for an unknown indication. On 26-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 26-Feb-2021, the patient experienced VENOUS THROMBOSIS LIMB (blood clot in left leg) (seriousness criterion medically significant). At the time of the report, VENOUS THROMBOSIS LIMB (blood clot in left leg) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Feb-2021, Fibrin D dimer: positive (Positive) positive. On 26-Feb-2021, Ultrasound Doppler: abnormal (abnormal) showed a dot in left leg.. Treatment was with Eliquis prescribed by her doctor. However the patient only took an aspirin daily. The blood clot resolved. The patient reported she was very healthy, runs daily, does not smoke, is not pregnant and is not on birth control pill (all of which are risk factors for DVT/blood clots). Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-081281 (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-081281:1st dose event</p>

COVID19 VACCINE	MODERNA	1249699-1	50-59 years	31-60 days	<p>Blood Clot in the Lower Left Lung; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Blood Clot in the Lower Left Lung) in a 57-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 008B21-2A and 010A21A) for COVID-19 vaccination. The patient's past medical history included Mastectomy bilateral on 20-Jan-2021 and Radiation therapy. Concurrent medical conditions included Breast cancer and Lung cancer (Has not been operated on as of yet). On 08-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 10-Apr-2021, the patient experienced PULMONARY EMBOLISM (Blood Clot in the Lower Left Lung) (seriousness criterion hospitalization). The patient was hospitalized on 10-Apr-2021 due to PULMONARY EMBOLISM. At the time of the report, PULMONARY EMBOLISM (Blood Clot in the Lower Left Lung) outcome was unknown. No concomitant medications reported. The patient developed a blood clot in the lower left lung, and was hospitalized. The doctor told her that because of cancer, radiation and recent mastectomy surgery she was at risk of developing blood clots. Treatment medication included apixaban for six months. The patient received both scheduled doses of mRNA-1273 prior to the event, therefore action taken with the drug in response to the event is not applicable. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Company Comment: Based on the current available information and temporal association between the use of the product and the onset date of the reported event, a causal relationship cannot be excluded. Patient's underlying cancer, radiation and recent mastectomy surgery were considered to be risk factors for developing blood clots.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the reported event, a causal relationship cannot be excluded. Patient's underlying cancer, radiation and recent mastectomy surgery were considered to be risk factors for developing blood clots.</p>
COVID19 VACCINE	MODERNA	1249700-1	60-64 years	31-60 days	<p>Deep vein thrombosis; Pulmonary embolism; Shortness of breath; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEEP VEIN THROMBOSIS (Deep vein thrombosis) and PULMONARY EMBOLISM (Pulmonary embolism) in a 61-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 031L20A and 012220A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included COVID-19 on 03-Jan-2021. Concomitant products included PARACETAMOL (TYLENOL), MAGNESIUM and VITAMIN B3 for an unknown indication. On 20-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 22-Feb-2021, the patient experienced DEEP VEIN THROMBOSIS (Deep vein thrombosis) (seriousness criterion hospitalization) and PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced DYSPNOEA (Shortness of breath). The patient was hospitalized for 2 days due to DEEP VEIN THROMBOSIS and PULMONARY EMBOLISM. At the time of the report, DEEP VEIN THROMBOSIS (Deep vein thrombosis) and PULMONARY EMBOLISM (Pulmonary embolism) outcome was unknown and DYSPNOEA (Shortness of breath) had not resolved. Not Provided The patient received Xarelto and IV blood thinner at hospital. Company comment: Based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded. This case was linked to MOD-2021-083811 (Patient Link); Sender's Comments: Based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine and onset of the reported events, a causal relationship cannot be excluded</p>

COVID19 VACCINE	MODERNA	1276756-1	65+ years	31-60 days	<p>Blood clot after receiving his second dose. Found out that he has Deep Vein Thrombosis (DVT); This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEEP VEIN THROMBOSIS (Blood clot after receiving his second dose. Found out that he has Deep Vein Thrombosis (DVT)) in a 92-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 030M20A and 027L20A) for COVID-19 vaccination. No medical history was provided by the reporter. Concomitant products included IRON for Iron supplementation, APIXABAN (ELIQUIS), MIDODRINE, CLOPIDOGREL BISULFATE (PLAVIX), HYDROXYCHLOROQUINE, METHYLPREDNISOLONE, MIRABEGRON (MYRBETRIQ), MONTELUKAST, TAMSULOSIN, VITAMIN D3 and CYANOCOBALAMIN (VIT B12) for an unknown indication. On 14-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 08-Mar-2021, the patient experienced DEEP VEIN THROMBOSIS (Blood clot after receiving his second dose. Found out that he has Deep Vein Thrombosis (DVT)) (seriousness criterion medically significant). At the time of the report, DEEP VEIN THROMBOSIS (Blood clot after receiving his second dose. Found out that he has Deep Vein Thrombosis (DVT)) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Mar-2021, Ultrasound scan: clear (normal) Clear. On 08-Mar-2021, the reporter noticed that the patient's left arm was swollen. The patient was taken to the emergency room and was diagnosed with deep vein thrombosis. The patient was discharged on the same day. The patient was put on apixaban 10mg and later switched to apixaban 5mg. The patient would be monitored until ??-Sep-2021. Company Comment: Very limited information regarding this event has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.</p>
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COVID19 VACCINE	MODERNA	1276790-1	50-59 years	31-60 days	<p>having a blood clot down whole right leg / up right side into right chest / under right breast / several clots in her lower abdomen; she almost died; urinary tract infection; right leg is very swollen; Kept losing consciousness/Passed out; hard time walking; had to use a walker; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (having a blood clot down whole right leg / up right side into right chest / under right breast / several clots in her lower abdomen), LOSS OF CONSCIOUSNESS (Kept losing consciousness/Passed out) and FEELING ABNORMAL (she almost died) in a 56-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 002b21a and 004m20a) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concomitant products included LEVOFLOXACIN, RIVAROXABAN (XARELTO), LISINAPRIL, HYDROCHLOROTHIAZIDE, OXYCODONE and LEVOTHYROXINE SODIUM (SYNTHROID) for an unknown indication. On 12-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 12-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 29-Mar-2021, the patient experienced GAIT DISTURBANCE (hard time walking) and WALKING AID USER (had to use a walker). On 12-Apr-2021, the patient experienced THROMBOSIS (having a blood clot down whole right leg / up right side into right chest / under right breast / several clots in her lower abdomen) (seriousness criteria hospitalization prolonged, medically significant, life threatening and intervention required) and LOSS OF CONSCIOUSNESS (Kept losing consciousness/Passed out) (seriousness criterion medically significant). 12-Apr-2021, the patient experienced FEELING ABNORMAL (she almost died) (seriousness criteria hospitalization and medically significant). On 26-Apr-2021, the patient experienced PERIPHERAL SWELLING (right leg is very swollen). On an unknown date, the patient experienced URINARY TRACT INFECTION (urinary tract infection). The patient was hospitalized from 12-Apr-2021 to 19-Apr-2021 due to FEELING ABNORMAL and THROMBOSIS. On 12-Apr-2021, LOSS OF CONSCIOUSNESS (Kept losing consciousness/Passed out) had resolved. At the time of the report, THROMBOSIS (having a blood clot down whole right leg / up right side into right chest / under right breast / several clots in her lower abdomen) was resolving and FEELING ABNORMAL (she almost died), URINARY TRACT INFECTION (urinary tract infection), GAIT DISTURBANCE (hard time walking), PERIPHERAL SWELLING (right leg is very swollen) and WALKING AID USER (had to use a walker) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 12-Apr-2021, Computerised tomogram: blood clots (abnormal) blood clot. On 12-Apr-2021, Ultrasound scan: blood clots (abnormal) blood clots. Action taken with mRNA-1273 in response to the events was not applicable. Patient stated she was in the ICU24-48 hours then transferred to another area of the hospital where she spent another 5-6days. She is still having to use a walker. Her right leg is very swollen. She has to walk and keep her right leg elevated. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, Further information has been requested. This case was linked to MOD-2021-090647 (Patient Link).; Sender's Comments: Based on the current available</p>
COVID19 VACCINE	MODERNA	1276794-1	65+ years	31-60 days	<p>Blood clot in leg; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clot in leg) in a 67-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 002B21A and 002A21A) for COVID-19 vaccination. No Medical History information was reported. On 26-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 2 dosage form. On 02-Apr-2021, the patient experienced THROMBOSIS (Blood clot in leg) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 02-Apr-2021 to 06-Apr-2021 due to THROMBOSIS. The patient was treated with Surgery (Angioplasty) for Thrombosis. On 06-Apr-2021, THROMBOSIS (Blood clot in leg) had resolved. Not Provided Concomitant product use was not provided by the reporter. The patient received both scheduled doses of mRNA-1273 prior to the events; therefore, action taken with the mRNA-1273 in response to the events was not applicable.; Sender's Comments: Based on current available information and the temporal association between product use and the stat date of the events a causal relationship cannot be excluded.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1028567-1	40-49 years	31-60 days	<p>CVA/thrombotic event. R sided weakness and sensory deficit. No preexisting risk factors. Hypercoaguable work up negative. Managed conservatively. Improvement without resolution of symptoms to date.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1032658-1	40-49 years	31-60 days	Had daily headaches after first dose of vaccine. For 3 weeks. Decided to skip the second dose because of that. Then had leg pain after nearly a month of the vaccine. Thought it was muscle pain but landed up in ER with shortness of breath and was diagnosed with DVT and large PE.
COVID19 VACCINE	PFIZER\BIONTECH	1057369-1	65+ years	31-60 days	Admitted to ER on 2/19/21. CT scan showed two pulmonary embolisms one in each lung. I'm currently on blood thinners.
COVID19 VACCINE	PFIZER\BIONTECH	1068762-1	65+ years	31-60 days	DEATH Narrative: patient's wife reported he had gone in an outside hospital, had held his brilinta as advised anticipating shoulder surgery ""and he threw a big clot and died. ""
COVID19 VACCINE	PFIZER\BIONTECH	1083010-1	50-59 years	31-60 days	DVT left leg with no prior history and no risk factors
COVID19 VACCINE	PFIZER\BIONTECH	1102925-1	65+ years	31-60 days	I started to have tingling sensation to my left leg. I have history of DVT, hemochromatosis, hyperthyroidism but is all managed. The issue is that the tingling sensation I was experiencing was moving in my left leg, was painful but then it went away. I went to the emergency room 02-25-2021 that started with a blood clot and they placed me on Xarelto medication. My PCP encouraged me to go to the ER. they did an U/S of my left lower extremity which showed blood clot. I am already on blood thinner medication and no one can explain or give me an answer as to why I have a blood clot after my vaccine when i am on blood thinner medication.
COVID19 VACCINE	PFIZER\BIONTECH	1112850-1	60-64 years	31-60 days	Severe, bilateral pulmonary emboli and 3 DVTs in left leg
COVID19 VACCINE	PFIZER\BIONTECH	1117857-1	65+ years	31-60 days	bilateral internal jugular thrombus and subclavian thrombus
COVID19 VACCINE	PFIZER\BIONTECH	1118021-1	50-59 years	31-60 days	On 1/27/2021, after having received Dose #2 of Pfizer Covid-19 vaccine on 01/07/21, I experienced severe calf pain while playing soccer. Over the next 2 weeks I experienced vascular claudication in that leg and was eventually diagnosed with arterial thrombus in Left tibioperoneal, anterior tibial/dorsalis pedis and posterior tibial arteries. I do not have any known predisposing conditions for arterial thrombus and no history of thromboembolic disease.
COVID19 VACCINE	PFIZER\BIONTECH	1126263-1	18-29 years	31-60 days	Bilateral pulmonary embolism. No clots detected in legs. Treatment: removed from birth control, Eliquis (10mg) for 3 months
COVID19 VACCINE	PFIZER\BIONTECH	1136194-1	65+ years	31-60 days	Bilateral DVTs in legs and Pulmonary Embolism diagnosed in Emergency Room on 03/13/2021.
COVID19 VACCINE	PFIZER\BIONTECH	1146205-1	65+ years	31-60 days	My wife had several blood clots in both lungs. She is now on blood thinners after spending 1 week in the hospital.
COVID19 VACCINE	PFIZER\BIONTECH	1149925-1	65+ years	31-60 days	Three weeks after my vaccine shot I was dx with bilateral pulmonary embolism; This is a spontaneous report from a contactable consumer (patient). A 70-years-old female patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration, administered in Arm Left on 13Feb2021 (Batch/Lot Number: EN6201) as SINGLE DOSE for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. None Known allergies. Patient was not pregnant. No other vaccine in four weeks. Historical vaccine included BNT162B2 (product=COVID 19, brand=Pfizer, lot number=EL9261) first dose administered in Left arm on 23Jan2021 01:15 PM. The patient experienced three weeks after her vaccine shot she was dx with bilateral pulmonary embolism on 16Mar2021 06:00 AM with outcome of not recovered. The event resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization, Prolongation of existing hospitalization (vaccine received during existing hospitalization), Life threatening illness (immediate risk of death from the event). The patient was hospitalized for the event for 4 days. The patient's hospitalization was prolonged as a result of this event. The patient underwent lab tests which included Nasal Swab (sars-cov-2 test): negative on 17Mar2021. No covid prior vaccination. The treatment received included anti-coagulative therapy.

COVID19 VACCINE	PFIZER\BIONTECH	1153517-1	50-59 years	31-60 days	Diagnosed in ER with 4 subsegmental pulmonary embolisms on 18Mar2021 shown with CT Scan with contrast; Shortness of Breath; This is a spontaneous report from a contactable consumer (patient). A 57-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: En5318), via an unspecified route of administration, administered in left arm on 04Feb2021 10:00 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had no known allergies. The patient was not pregnant at the time of report. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: El3249) administered on the left arm on 14Jan2021 10:00 AM for COVID-19 immunization. The patient was diagnosed in Emergency room (ER) with 4 subsegmental pulmonary embolisms on 18mar2021 16:00 shown with CT scan with contrast and experienced shortness of breath on 18Mar2021 16:00. Prior to vaccination, the patient was not diagnosed with COVID. Patient was tested COVID post vaccination. The patient underwent lab tests and procedures which included CT scan with contrast: 4 subsegmental pulmonary embolisms on 18Mar2021, and nasal swab: negative on 14Jan2021. Therapeutic measures were taken as a result of the events and included treatment with apixaban (ELIQUIS). Facility type vaccine was Nursing Home. The event resulted in doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent case, life threatening illness (immediate risk of death from the event). The outcome of the events were recovering.
COVID19 VACCINE	PFIZER\BIONTECH	1153533-1	Unknown	31-60 days	blood clots in the lungs; certain cardiac problems; On 05MAR2021, he tested positive to COVID; On 05MAR2021, he tested positive to COVID; This is a spontaneous report from a non-contactable consumer (patient). A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), second dose via an unspecified route of administration on 15Jan2021 (Batch/Lot number was not reported), first dose via an unspecified route of administration on 25Dec2020 (reported as 25Dec2021; Batch/Lot number was not reported); both as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. On 05Mar2021, he tested positive to COVID. It's now been 16 days he has COVID. He stated he has blood clots in the lungs and certain cardiac problems on an unspecified date. The patient underwent lab tests and procedures which included sars-cov-2 test: positive on 05Mar2021. The outcome of the events was unknown. No further follow up excepted. Batch/lot number cannot be obtained.
COVID19 VACCINE	PFIZER\BIONTECH	1158868-1	65+ years	31-60 days	Nausea, vomiting - Blood clot on kidney. No hx of clotting issues prior.
COVID19 VACCINE	PFIZER\BIONTECH	1172562-1	65+ years	31-60 days	on 3-11-2021 pt presented to PCP and reported onset around the last week of February 2021. PCP directed pt to ED for urgent evaluation pt was hospitalized x 2 day, treated and sent home on Eliquis.
COVID19 VACCINE	PFIZER\BIONTECH	1182613-1	65+ years	31-60 days	He was admitted with acute right sided pulmonary embolus and extensive left leg DVT. His vaccine second dose was mid Febrary ( I do not have the exact date). He had brief swelling in left leg a few days after vaccination that resolved. This recurred 4/3/21 and he was admitted 4/6/21.
COVID19 VACCINE	PFIZER\BIONTECH	1191928-1	Unknown	31-60 days	was diagnosed with multiple bilateral pulmonary blood clots; This is a spontaneous report from a contactable Nurse (patient's wife). A 73-year-old male patient (Husband) received BNT162B2 (PFIZER-BIONTEC COVID-19 mRNA VACCINE, Solution for injection, lot number and expiry dates were not provided), via an unspecified route of administration, on 06Feb2021, as a single dose for COVID-19 immunisation. Patient's medical history and concomitant medications were not reported. It was reported that patient received his first COVID vaccine dose on 06Feb2021. On 10Mar2021 he was admitted to the hospital for trouble breathing and was diagnosed with multiple bilateral pulmonary blood clots. He was hospitalized from 10Mar2021 to 13Mar2021. Seriousness of the events was reported as hospitalization. Outcome of the events was unknown. Information on the Lot/Batch number has been requested.; Sender's Comments: Based on temporal association, a contributory role of multiple bilateral pulmonary blood clots cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified.

COVID19 VACCINE	PFIZER\BIONTECH	1201486-1	30-39 years	31-60 days	1st covid vaccine given on 1/18/21, 2nd covid vaccine given on 2/8/21. On 2/17/21 I was experiencing mild shortness of breath, but did not seek medical help as the symptoms would come and go and were not severe. On 2/22/21 I had an outpatient hernia repair surgery. On 2/23/21, I began experiencing shortness of breath and dizziness on exertion. This continued throughout the next many days. On 3/1/21 I had sudden onset of dizziness, tachycardia, shortness of breath. I was admitted to the hospital with bilateral DVT and PE.
COVID19 VACCINE	PFIZER\BIONTECH	1205585-1	65+ years	31-60 days	Blood clot in the middle cerebral artery leading to ischemic stroke
COVID19 VACCINE	PFIZER\BIONTECH	1206312-1	65+ years	31-60 days	Lung blood clot found after emergency room visit experiencing shortness of breath 03/04. Tennis ball size neck lymph node swelling starting 02/25. Joint pain and swelling starting 2/22
COVID19 VACCINE	PFIZER\BIONTECH	1209523-1	65+ years	31-60 days	Had DVT (left leg) and PE, never had that before and 18mos prior had ultrasound of leg veins showing no problems,
COVID19 VACCINE	PFIZER\BIONTECH	1210450-1	30-39 years	31-60 days	Within one month after the first vaccination (2/8/21) migraine intensity increased significantly. Second vaccine was on 3/22/21. Migraine became so unbearable that I was admitted to ED on 3/25/21.
COVID19 VACCINE	PFIZER\BIONTECH	1212117-1	60-64 years	31-60 days	Right leg DVT, bilateral pulmonary emboli, left ventricular apical thrombus
COVID19 VACCINE	PFIZER\BIONTECH	1218764-1	65+ years	31-60 days	Patient with Hx of AML received 1st dose COVID vaccine 2/10/2021, 2nd dose 3/4/2021. She developed DVT of the right leg, AML relapse. The patient has been diagnosed with AML back in 2016 and underwent several lines of therapy including chemotherapy with 7 and 3 and the last treatment was decitabine with maintenance treatment with ivosidenib. Having severe leukocytosis and right-sided leg edema with DVT raised concern about blast crisis and leukostasis. Patient was admitted to hospital and received. ceftriaxone and azithromycin for possible pneumonia. She underwent leukopheresis on the 4/6/2021, 4/7/2021. Patient received IV heparin gtt for DVT but later on was on hold given worsening thrombocytopenia. She was transferred from one hospital to another hospital. I do not think the development of DVT was due to COVID vaccine. But prior to COVID vaccine, patient was in AML remission.
COVID19 VACCINE	PFIZER\BIONTECH	1219318-1	65+ years	31-60 days	In march I started becoming SOB and it continued to progress. It became so bad that I could only walk about 5-10 feet before becoming totally exhausted, needing to sit down for a few minutes. My heart rate remained sinus-tach running up to 120's. On March 4, 2021 I had an appointment with Dr. He sent me to the Hospital to have a CTA. The test was positive for a MASSIVE bilateral PE. Doppler studies of my lower extremities showed a partially occluded Palpitate vein in my right leg. I was admitted to the hospital and started on Heparin IV. I was also taken to the Cath- lab where I underwent a Thrombectomy of my right lung. The Cath- lab quit working so the procedure was stoped and the left lung was not treated. On admission to the hospital my O2 sat was 97%. After the thrombectomy my O2 sat went to 83%. I was placed on Hiigh-flow O2 via nasal cannula. On March 8th I was started on Lovenox SQ for 30 day and discharged from the hospital on March 9th. I am now on Eliquis 5 mg bid and doing much better.
COVID19 VACCINE	PFIZER\BIONTECH	1261815-1	40-49 years	31-60 days	Portal Vein Thrombosis; This is a spontaneous report from a contactable consumer (the patient). A 47-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: 9809), via an unspecified route of administration in left arm on 10Feb2021 at age of 47-year-old at single dose for COVID-19 immunisation. Medical history included back pain/stenosis and high cholesterol. No known allergies. The patient did not have COVID prior vaccination. Concomitant medications (Other medications in two weeks) included oxycodone taken for an unspecified indication from an unspecified date; docusate sodium (COLACE) taken for an unspecified indication from an unspecified date; pregabalin (LYRICA) taken for an unspecified indication from an unspecified date; atorvastatin calcium (LIPITOR ORIFARM) taken for an unspecified indication from an unspecified date; naloxegol oxalate (MOVANTIK) taken for an unspecified indication from an unspecified date. No other vaccine in four weeks. The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EL 3247) via an unspecified route of administration in left arm on 20Jan2021 08:00AM for COVID-19 immunisation. The patient experienced portal vein thrombosis on 26Mar2021. The event resulted in: Emergency room/department or urgent care, Hospitalization (for 3 days), Life threatening illness (immediate risk of death from the event)]. Therapeutic measures were taken as a result of the event included treated with Anti Coagulation. Nasal Swab test was done on 02Apr2021 with result of ""negative"". The outcome of the event was recovering.""

COVID19 VACCINE	PFIZER\BIONTECH	1265912-1	60-64 years	31-60 days	<p>DVT; This is a spontaneous report from a contactable physician (patient). This 60-year-old male patient received 2nd dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number Ek4176) at single dose via an unknown route in left arm on 18Jan2021 for Covid-19 immunization. Medical history included factor 5 leiden and prior DVT. Patient did not have Covid prior vaccination. Patient had no known allergies. Concomitant drug was not provided. Historical vaccine included 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: Eh9899) on 26Dec2020 for Covid-19 immunisation. On 08Mar2021, patient experienced DVT which resulted in doctor or other healthcare professional office/clinic visit. Treatment included blood thinner. Outcome of the event was unknown. Patient did not have Covid tested post vaccination.; Sender's Comments: Based on the information currently available, the event deep vein thrombosis was most likely associated with the patient's underlying medical condition and was unrelated to Bnt162b2 vaccine. Case will be re-assessed upon the additional information provided. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1265965-1	18-29 years	31-60 days	<p>PE; This is a spontaneous report from a contactable Nurse. A 28-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: Ek9231), via an unspecified route of administration, administered on the left arm, at the age of 28 years, on 12Jan2021 at a SINGLE DOSE for covid-19 immunisation. Medical history included asthma, angioliopoma, labral surgery to hip, drug hypersensitivity to penicillins; all from an unknown date and unknown if ongoing. Concomitant medications included ethinylestradiol, norethisterone acetate (JUNEL FE 1/20) and cetirizine hydrochloride (ZYRTEC [CETIRIZINE HYDROCHLORIDE]); both taken for an unspecified indication, start and stop date were not reported. The patient previously took amoxicillin and experienced drug hypersensitivity, bactrium ds and experienced drug hypersensitivity, doxycycline and experienced drug hypersensitivity. The patient received first dose of COVID vaccine BNT162B2 (lot number= Ej1685) at the age of 28 years on 22Dec2020 on the left arm at single dose for COVID-19 immunization. The patient reported that 2 weeks after the second vaccine, she underwent hip labral surgery and suffered a PE on 22Feb2021. She was not sure if the vaccine could have contributed to the PE or just the surgery but wanted to report just incase. She was taking aspirin to prevent DVT's. The patient was hospitalized for pe (pulmonary embolism) for 3 days. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 22Feb2021. Therapeutic measures (DOAC) were taken as a result of pe (pulmonary embolism). The outcome of the event was recovering.; Sender's Comments: The event pulmonary embolism is likely an intercurrent medical condition and unrelated to BNT162B2. Patient's hip surgery two weeks after the vaccine might have contributed to the event onset. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1265968-1	65+ years	31-60 days	<p>This is a spontaneous report from a contactable consumer (patient). A 73-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), second dose via an unspecified route of administration (injection), administered in the right arm on 12Feb2021 at 13:00 (batch/lot number: EL9267) as a single dose for COVID-19 immunization. Medical history included rheumatoid arthritis from 1991 and ongoing (diagnosed 30 years ago; doctor said that he didn't know if she has RA because she's taken all of those infusions and it may just be severe osteoarthritis), ongoing thyroid (disorder), thyroid was removed, knee replacement left leg from 2020 (she had knee replacement last year on her left knee), Achilles tendon tear - reported that she had to have surgery last to repair her right Achilles tendon as it tore, cholesterol (abnormal) from 1991 and ongoing (diagnosed with cholesterol problems 30 years ago), ongoing depression (diagnosed with depression a couple years ago), ongoing sleep problems (experienced sleep problems for a long time), blood pressure (abnormal) from 2013 and ongoing (diagnosed with blood pressure problems 8 years ago), physical therapy, lymphedema, and unable to recall exact dates. There was no family medical history. No prior vaccinations (within 4 weeks). Concomitant medications included amitriptyline taken to help her sleep from an unspecified start date and ongoing (she has been taking this medication for years and years); folic acid taken for arthritis from an unspecified start date and ongoing (she has been taking this medication for years and years); levothyroxine taken for thyroid, start and stop date were not reported (she has been taking this medication for years and years); chlordiazepoxide (LIBRIUM) taken for sleep from an unspecified start date and ongoing (she has been taking this medication for years and years); losartan taken for blood pressure from an unspecified start date and ongoing (she has been taking this medication for years and years); meloxicam taken for arthritis from an unspecified start date and ongoing (began taking for 10 or 15 years after switching from celecoxib); metoprolol taken for blood pressure from an unspecified start date and ongoing (she has been taking this medication for years and years); omeprazole taken for stomach from an unspecified start date and ongoing (helps her stomach with all of the medications she has to take); pravastatin taken for cholesterol from an unspecified start date and ongoing (she has been taking this medication for years and years); desvenlafaxine succinate (PRISTIQ) taken for depression from an unspecified start date and ongoing (she started taking over a year ago, a year and a half or maybe two years ago); levothyroxine sodium (SYNTHROID) taken since thyroid was removed from an unspecified start date and ongoing (she has been taking since 15 years ago, for a long time); temazepam taken to help her sleep from an unspecified start date and ongoing (she has been taking this medication for years and years); cholecalciferol (VITAMIN D3) taken for an unspecified indication from an unspecified start date and ongoing (she has been taking this medication for years and years). The patient previously took BNT162B2 first dose on 21Jan2021 via injection in the right arm (lot number: EL3047 or EL3247; expiration date unknown) for COVID-19 immunization; and celecoxib (CELEBREX). The patient experienced extensive deep vein thrombosis on 06Apr2021; leg pain and feet swollen/ leg was like a balloon/ leg started to swell on 05Apr2021; throat hurts and tired on an unspecified date. The patient was calling about the Pfizer Covid-19 vaccine. She reported that she and her husband</p>
COVID19 VACCINE	PFIZER\BIONTECH	1266072-1	65+ years	31-60 days	<p>Major PE detected on CT Scan at an ER; This is a spontaneous report from a contactable consumer (patient). A 74-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EM9810 ) on 09Feb2021 at 11:00 (at 74 years) at single dose in left arm for covid-19 immunisation. The patient medical history and concomitant medications were not reported. Patient took the first dose of the vaccine (lot EL3247) in Jan2021 at 11:00 am (at 74 years) in left arm for covid-19 immunisation. No COVID prior vaccination. On 31Mar2021 at 12:00 the patient experienced major pulmonary embolism (PE) detected on computerised tomogram (CT) Scan at an emergency room (ER). The event required doctor or other healthcare professional office/clinic visit and emergency room/department or urgent care. Event was serious due to hospitalization and life threatening illness. Patient was hospitalized in 2021 for 4 days. Patient was treated with Heparin and Eliquis. Patient was tested post vaccination: Nasal Swab was done on 31Mar2021 and was negative. The outcome of the event was recovering.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1269718-1	40-49 years	31-60 days	Developed a blood clot in peroneal vein of left leg.; This is a spontaneous report from a contactable consumer. A 48-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: ER8732), via an unspecified route of administration, administered on the right arm, at the age of 48 years, on Mar2021 at a SINGLE DOSE for covid-19 immunisation. Medical history included drug hypersensitivity to Penicillin from an unknown date and unknown if ongoing. Concomitant medications included vitamin b complex (VITAMIN B); astragalus mongholicus (ASTRAGALUS 6000); lysine (LYSINE) and multivitamins; all taken for an unspecified indication, start and stop date were not reported. The patient developed a blood clot in peroneal vein of left leg on 02Apr2021 06:00. The patient underwent lab tests and procedures which included sars-cov-2 test: negative on 07Apr2021. Therapeutic measures (blood thinners) were taken as a result of developed a blood clot in peroneal vein of left leg. The outcome of the event was recovered with sequelae.
COVID19 VACCINE	PFIZER\BIONTECH	1284766-1	50-59 years	31-60 days	I had a stroke. The blood clot is on the left side of the brain which has affected the right side of my body: right leg, right foot, right arm, right hand, and the right side of my face.; I had a stroke. The blood clot is on the left side of the brain which has affected the right side of my body: right leg, right foot, right arm, right hand, and the right side of my face.; This is a spontaneous report from a contactable consumer. A non-pregnant 53-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 2 via an unspecified route of administration, administered in left arm on 12Feb2021 15:00 (Batch/Lot Number: EL9269) as single dose (at the age of 53 years old) for COVID-19 immunisation. Medical history included depression, pre-diabetes and hysterectomy from 2003 hormones due to hysterectomy in 2003. Concomitant medications included metformin, semaglutide (OZEMPIC), estradiol, amfetamine aspartate, amfetamine sulfate, dexamphetamine saccharate, dexamphetamine sulfate (ADDERALL), lisdexamphetamine mesilate (VYVANSE) and ascorbic acid (C [ASCORBIC ACID]), all taken for an unspecified indication, start and stop date were not reported. The patient previously took BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 (lot number=EL9262) at 20Jan2021 03:00 AM, on the right arm for COVID-19 immunisation. The patient stated on 24Mar2021, ""I had a stroke. The blood clot is on the left side of the brain which has affected the right side of my body: right leg, right foot, right arm, right hand, and the right side of my face."" Patient received blood thinners as treatment. The patient had emergency and physician visit. The patient was hospitalized for 2 days. The outcome of the event was not recovered.""
COVID19 VACCINE	UNKNOWN MANUFACTURER	1110945-1	65+ years	31-60 days	Saddle pulmonary embolism, increasing shortness of breath, COVID positive test but seems to have symptoms from the pulmonary embolism and not COVID, no ground glass opacities in lungs seen on imaging., still currently in the hospital getting treatment for clots, currently day two
COVID19 VACCINE	UNKNOWN MANUFACTURER	1208355-1	60-64 years	31-60 days	J&J Covid vaccination fine symptoms started 10 days later
COVID19 VACCINE	UNKNOWN MANUFACTURER	1214198-1	30-39 years	31-60 days	Patient presented with acute onset leg pain and new diagnosis of DVT 5 wks post covid 19 J&J vaccine. 36 yo female with a history of a dvt in 2002 when she was on birth control (and became pregnant). Unknown if this is a true ADR or incidental finding
COVID19 VACCINE	UNKNOWN MANUFACTURER	1240493-1	30-39 years	31-60 days	6 weeks after administration of COVID-19 vaccine developed DVT in right subclavian vein which progressed to a subsegmental PE 2 days after confirmation by ultrasound despite being on Eliquis.
COVID19 VACCINE	UNKNOWN MANUFACTURER	1247588-1	65+ years	31-60 days	Shortness of breath in early March, hospitalized on 3/17/2021, was COVID positive and was found to have pulmonary emboli
COVID19 VACCINE	JANSEN	1269209-1	60-64 years	61-120 days	On Jan. 26, 2021, I had an accident at home an suffered broken ankle, tibia and fibula broken from tarsus. I was rushed to hospital and had ORIF surgery. I later found out the surgeons failed to order blood thinners and about a month later, I was rushed to the hospital with 5 blood clots, one in each lobe or each lung and one forming in the calf muscle on the left leg. I have been taking Eliquis since late February and will be on it through May. I have had an echocardiogram which was normal but the doppler I had on my legs may have indicated the problem is still on-going. I don't know yet. I did contract JCCT to ask if I should get checked out due to recent clotting incidents and was told I did not. I decided I should report it anyway and my clotting situation probably has nothing to do with vaccine but I just want to make sure.
COVID19 VACCINE	MODERNA	1126277-1	30-39 years	61-120 days	STEMI on 3/18/2021. Thrombosis in LAD. Minimal coronary artery disease on cath.
COVID19 VACCINE	MODERNA	1176103-1	18-29 years	61-120 days	Pelvic blood clot in right common iliac artery

COVID19 VACCINE	MODERNA	1182262-1	65+ years	61-120 days	Diagnosed with a dvt blood clot in my left leg on 04/02/2021. On eliquis and warfarin.
COVID19 VACCINE	MODERNA	1182712-1	65+ years	61-120 days	She had both doses of Moderna COVID vaccine and finished the series in mid February. She was admitted 4/5/21 with bilateral PE and popliteal vein thrombus in the left leg. She had been sedentary the week before with a ""cold"" and has morbid obesity.""
COVID19 VACCINE	MODERNA	1190026-1	65+ years	61-120 days	On April 4, 2021, my mother, was diagnosed with a cerebral venous sinus thrombosis (CVST). I figured I would report this, as I am seeing more and more reports about the vaccines tied to this rare brain blood clot: ""Moderna?s rival mRNA shot has been linked to five CVST cases out of 4 million vaccinated."" ""More than a dozen countries worldwide temporarily stopped administering the Oxford-AstraZeneca COVID vaccine, notes the Association of American Physicians and Surgeons (AAPS), because of deaths from blood clotting disorders, with either clots or excessive bleeding. Some patients experienced the extremely rare event of clots in the veins that drain blood from the brain (venous sinus thrombosis).""
COVID19 VACCINE	MODERNA	1204779-1	65+ years	61-120 days	Clot blood; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Clot blood) in an 80-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 031M20A) for COVID-19 vaccination. The patient's past medical history included No adverse event (No medically reported history). On 20-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 17-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 31-Mar-2021, the patient experienced THROMBOSIS (Clot blood) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Clot blood) outcome was unknown. The patient was diagnosed with blood clots in legs and lung. Very limited information regarding this event has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.
COVID19 VACCINE	MODERNA	1212491-1	65+ years	61-120 days	Patient presented to our facility due to progressive swelling of his LLE. Patient is an avid cyclist and reports he began training again for the spring season approx. 1 mo ago. He had L calf tightness present for a few weeks as well as slightly painful knees which he attributed to his age and mild deconditioning over the winter. He traveled with infrequent stops on 4/2/2021 to visit family. He continued to have discomfort and increasing ankle pain, thus presented to ER. LE ultrasound venous dopplers performed showing extensive DVT: L femoral, popliteal, posterior tibial and peroneal veins. CT also demonstrated acute PE w/in distal R and L main pulm artery and w/in bilateral segmental and subsegmental pulm arteries involving all the lobes. Patient had remote history of LE DVT in 2017 after mild bumping of leg and placed on Xarelto for 6 mo. Had genetic testing completed at that time which was negative. He has had no clotting issues since. ( Received Moderna COVID-19 vaccines on 2/3/21 and 3/3/21. Reports brain fog and fatigue approx. 20 hours after vaccination followed by the above.) Patient discharged on rivaroxaban.
COVID19 VACCINE	MODERNA	1213276-1	65+ years	61-120 days	Patient had headache after each dose of vaccine. As this is a common reaction to vaccine, patient was not concerned. However, after headache worsened/did not resolve, patient you went to doctor, and doctor ordered MRI. Patient received phone call to go to ER d/t MRI results of blood clots in brain on 4/8/2021. Patient was hospitalized for one day and placed on high dose eliquis. Patient then went home. Patient woke up with rapid heart beat and chest pain on 4/12/2021 and was readmitted to the hospital for an additional day.

COVID19 VACCINE	MODERNA	1245433-1	50-59 years	61-120 days	<p>pulmonary embolism; This spontaneous case was reported by a consumer and describes the occurrence of PULMONARY EMBOLISM (pulmonary embolism) in a 59-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 00922436 and 012D20A) for COVID-19 vaccination. The patient's past medical history included No adverse event (No relevant medical history provided). On 07-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 07-Apr-2021, the patient experienced PULMONARY EMBOLISM (pulmonary embolism) (seriousness criteria hospitalization and medically significant). The patient was hospitalized from 07-Apr-2021 to 09-Apr-2021 due to PULMONARY EMBOLISM. On 09-Apr-2021, PULMONARY EMBOLISM (pulmonary embolism) had resolved. The patient's medical history and relevant concomitant medications weren't reported Treatment medication included the Xarelto. Company comment:Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-077614 (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-077614:</p>
COVID19 VACCINE	MODERNA	1245447-1	50-59 years	61-120 days	<p>had another stroke; blood clots in brain; Difficult to control right hand; difficult to speak; had a stroke and went to the hospital; This spontaneous case was reported by a nurse (subsequently medically confirmed) and describes the occurrence of CEREBROVASCULAR ACCIDENT (had another stroke), CEREBRAL THROMBOSIS (blood clots in brain), TRANSIENT ISCHAEMIC ATTACK (had a stroke and went to the hospital), DYSKINESIA (Difficult to control right hand) and DYSARTHRIA (difficult to speak) in a 56-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 012M20A and 039A20A) for COVID-19 vaccination. The patient's past medical history included No adverse event (No reported medical history). On 12-Dec-2020, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Jan-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 21-Feb-2021, the patient experienced TRANSIENT ISCHAEMIC ATTACK (had a stroke and went to the hospital) (seriousness criterion medically significant). On 23-Feb-2021, the patient experienced CEREBROVASCULAR ACCIDENT (had another stroke) (seriousness criteria hospitalization and medically significant), CEREBRAL THROMBOSIS (blood clots in brain) (seriousness criterion hospitalization), DYSKINESIA (Difficult to control right hand) (seriousness criterion hospitalization) and DYSARTHRIA (difficult to speak) (seriousness criterion hospitalization). The patient was hospitalized from 23-Feb-2021 to 26-Feb-2021 due to CEREBRAL THROMBOSIS, CEREBROVASCULAR ACCIDENT, DYSARTHRIA and DYSKINESIA. At the time of the report, CEREBROVASCULAR ACCIDENT (had another stroke), CEREBRAL THROMBOSIS (blood clots in brain), TRANSIENT ISCHAEMIC ATTACK (had a stroke and went to the hospital), DYSKINESIA (Difficult to control right hand) and DYSARTHRIA (difficult to speak) outcome was unknown. Not Provided For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication use was not reported. Treatment for the events included Plavix; Sender's Comments: Although a temporal association exist, critical details such as the patient's medical history, list of concomitant medication are lacking . Pending additional information, causality with mRNA-1273 administration cannot be confirmed for all events.</p>

COVID19 VACCINE	MODERNA	1276717-1	65+ years	61-120 days	<p>blood clots in both legs; heart attack/blood clot in heart; Blood clots in lungs/shortness of breath; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (blood clots in both legs), MYOCARDIAL INFARCTION (heart attack/blood clot in heart) and PULMONARY EMBOLISM (Blood clots in lungs/shortness of breath) in a 72-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 8077727310 and 012LZ0A) for COVID-19 vaccination. No Medical History information was reported. On 25-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 09-Apr-2021, the patient experienced THROMBOSIS (blood clots in both legs) (seriousness criteria hospitalization prolonged and life threatening), MYOCARDIAL INFARCTION (heart attack/blood clot in heart) (seriousness criteria hospitalization prolonged and life threatening) and PULMONARY EMBOLISM (Blood clots in lungs/shortness of breath) (seriousness criteria hospitalization prolonged and life threatening). The patient was hospitalized on 09-Apr-2021 due to MYOCARDIAL INFARCTION, PULMONARY EMBOLISM and THROMBOSIS. At the time of the report, THROMBOSIS (blood clots in both legs), MYOCARDIAL INFARCTION (heart attack/blood clot in heart) and PULMONARY EMBOLISM (Blood clots in lungs/shortness of breath) outcome was unknown. No concomitant medications were reported. Treatment of the events included Xarelto and unspecified IV medications. Action taken with mRNA-1273 in response to the events was not applicable. Company Comment: Very limited information regarding this event/s has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1065432-1	65+ years	61-120 days	<p>multiple bilateral Pulmonary emboli; pulmonary hypertension; short of breath; right heart strain; This is a spontaneous report from a contactable nurse. A 68-year-old female patient received first dose bnt162b2 (PFIZER COVID 19 VACCINE, lot number=EH9899), via an unspecified route of administration at right arm on 22Dec2020 08:00 AM at single dose for COVID-19 immunisation. Medical history included uveitis, arthritis and known allergies: pine nuts. The patient did not have COVID prior vaccination. The patient did not test for COVID post vaccination. The patient was not pregnant. Concomitant medication included prednisone (eye gtt), naproxen as needed (PRN) less than weekly. The patient previously took theophylline and experienced allergies. The day after getting the first dose of vaccine the patient worked all day in another (clinic withheld). She felt well all day, but at 6 pm when she left to go to her car she was so short of breath she had to stop twice to get there. Subsequent work up has shown that she had multiple bilateral Pulmonary emboli resulting in pulmonary hypertension and right heart strain. Adverse event start date was 23Dec2020. Adverse event start time was 06:00 PM. The adverse events resulted in: [Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization for 1 day, Life threatening illness (immediate risk of death from the event)]. Therapeutic measures were taken as a result of the events included Lovenox and Eliquis. The outcome of the event was recovering.; Sender's Comments: Based on available information and known drug profile the reported events are unlikely related to bnt162b2. These are probably intercurrent medical condition. Case will be reassessed if additional information is received. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1110877-1	60-64 years	61-120 days	EE admitted to hospital 3/18/2021 with ""blood clots""
COVID19 VACCINE	PFIZER\BIONTECH	1131976-1	40-49 years	61-120 days	Shortness of breath, Diffuse Pulmonary Embolism with Ground glass opacities, happened over course of 1 week
COVID19 VACCINE	PFIZER\BIONTECH	1187889-1	40-49 years	61-120 days	pulmonary embolism, symptomatic
COVID19 VACCINE	PFIZER\BIONTECH	1201409-1	40-49 years	61-120 days	Delivered preterm infant (stillbirth) at 24 weeks on March 9, 2021. Infant had IUGR noted at 19 weeks. Placenta showed 2 blood clots restricting blood flow at delivery. Mother with no known clotting disorders. 2 prior healthy infants.

COVID19 VACCINE	PFIZER\BIONTECH	1213564-1	65+ years	61-120 days	The patient was admitted to hospital from 2/24/2021 until 3/6/2021 for AMS, diagnosed with UTI. He had an MRI on 3/3/2021 that incidentally showed a nonocclusive thrombus in the right dural venous sigmoid sinus, which extends to the right jugular vein. He is being treated with apixaban. It is unclear if this is coincidental or somehow related to the vaccine.
COVID19 VACCINE	PFIZER\BIONTECH	1224392-1	65+ years	61-120 days	Developed a blood clot behind the left knee; This is a spontaneous report from a contactable consumer. A 72-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration, administered in Arm Left on 18Jan2021 16:00 (Batch/Lot Number: EL3246) as SINGLE DOSE, dose 2 via an unspecified route of administration, administered in Arm Left on 17Feb2021 (Batch/Lot Number: EN6200) as SINGLE DOSE for covid-19 immunisation. Medical history included Known allergies: Feathers. Concomitant medication included cetirizine hydrochloride (ZYRTEC [CETIRIZINE HYDROCHLORIDE]) taken for an unspecified indication, start and stop date were not reported. On 22Mar2021 18:00, the patient Developed a blood clot behind the left Knee. Ae resulted in : [Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care]. The patient received treatment for the event: Blood Thinner Meds and Compression Stocking. The outcome of the event was not recovered. The patient did not have covid prior vaccination, and the patient was not COVID tested post vaccination.
COVID19 VACCINE	PFIZER\BIONTECH	1235809-1	65+ years	61-120 days	Acute pulmonary embolism; cardiac arrest; atrial fibrillation with rvr; pulmonary infiltrate right upper lobe; hyperglycemia; This is a spontaneous report from a contactable Nurse (patient herself). A 68-year-old female patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration, administered in Arm Right on 22Dec2020 11:45 (Batch/Lot Number: EH9899) as SINGLE DOSE for covid-19 immunisation at a hospital, at 68 years old. Patient is not pregnant. Medical history included hypothyroid from an unknown date. Patient has no COVID prior vaccination and has not tested for COVID post vaccination. Patient has no known allergies. Concomitant medication included levothyroxine sodium (SYNTHROID) taken for an unspecified indication, start and stop date were not reported. The patient experienced acute pulmonary embolism, cardiac arrest, atrial fibrillation with rvr, pulmonary infiltrate right upper lobe, hyperglycemia on 21Feb2021 05:00 which required Emergency room/department or urgent care. The patient was hospitalized (unspecified date) due to the events for 4 days. Therapeutic measures were taken included cardioversion twice and embolectomy. Outcome of the events was recovered with sequelae (with lasting effects) on an unspecified date. Seriousness criteria was hospitalization and life-threatening.; Sender's Comments: Based on the current available information, the reported events are most likely related to an intercurrent or underlying condition which is not related to the suspected drug. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified.
COVID19 VACCINE	PFIZER\BIONTECH	1237884-1	65+ years	61-120 days	Resident have had multiple PNA tx with IM Rocephin and IV Zosyn, Difficulty in swallowing, Elevated HCV RNA, 02/15 PCR Quant, ER visit following weakness and involuntary UE movements/jerking. Elevated amonia levels controlled with use of Lactulose. 02/22/2021 RUE and RLE extensive DVT. Worsening pressure wound and development of arterial wounds. Admitted to Hospice on 03/31/2021. Resident deceased on 04/03/2021.
COVID19 VACCINE	PFIZER\BIONTECH	1256737-1	65+ years	61-120 days	Died blood clot in brain

COVID19 VACCINE	PFIZER\BIONTECH	1276281-1	Unknown	61-120 days	<p>Blood clot in the right eye; This is a spontaneous report from a contactable consumer(patient) based on information received by Pfizer, license party for apixaban (ELIQUIS). This spontaneous case was reported by a consumer and describes the occurrence of OPHTHALMIC VEIN THROMBOSIS (Blood clot in the right eye) in male patient of an unknown age who received apixaban (Eliquis) for an unknown indication. CO-SUSPECT PRODUCTS included Covid-19 Vaccine for an unknown indication. On an unknown date, the patient started Eliquis (unknown route). On 07-Jan-2021, the patient started Covid-19 Vaccine (unknown route). In April 2021, the patient experienced OPHTHALMIC VEIN THROMBOSIS (seriousness criterion medically significant). The action taken with Eliquis (Unknown) was unknown. At the time of the report, OPHTHALMIC VEIN THROMBOSIS outcome was unknown. The consumer received his first Pfizer covid 19 shot on 07-Jan-2021 and the second one on 28-Jan- 2021, and 10 days prior to this report he got a blood clot in his right eye. He takes a blood thinner and remarks this should keep him from getting blood clots, should not it. Blood thinner provided was Eliquis. The event was related to covid 19 vaccine and causality with Eliquis was not provided. For Eliquis (Unknown), the reporter did not provide any causality assessments. This case was received via pfizer. BMS Medical Evaluation Comment: This patient had ophthalmic vein thrombosis while on therapy with apixaban and after taking covid 19 vaccine. Underlying thromboembolic risk as ascertained by the use of apixaban is a significant factor that likely predisposed the patient to develop ophthalmic vein thrombosis and considered not related to apixaban therapy. Causality Assessment: For apixaban: the causal relationship of the event Ophthalmic vein thrombosis with the suspect product apixaban was not provided Per Reporter; the causal relationship of the event Ophthalmic vein thrombosis with the suspect product apixaban was Not Related Per Company (Bristol-Myers Squibb)</p>
COVID19 VACCINE	PFIZER\BIONTECH	1288839-1	65+ years	61-120 days	<p>Systemic: Blood Disorder (diagnosed by MD)-Severe, Additional Details: Patient passed away on 4/23/21 and had blood clots throughout body. Patient did not have any other symptoms that were reported. Patients family requested a VAERS report be submitted.</p>

COVID19 VACCINE	UNKNOWN MANUFACTURER	1167457-1	Unknown	61-120 days	<p>clot; swelling and pain in foot / foot was swollen/swelling and pain in calf; swelling and pain in Ankle/ Ankle was swollen; pain in foot, calf and ankle / foot was sore; pain in foot, calf and ankle / foot was sore; This case was reported by a consumer via other and described the occurrence of clot blood in a female patient who received Herpes zoster (Shingles vaccine) for prophylaxis. Co-suspect products included Flu Seasonal QIV Dresden (Influenza vaccine Quadrivalent unspecified season) for prophylaxis and COVID 19 VACCINE for prophylaxis. Concomitant products included COVID 19 VACCINE. In November 2020, the patient received Shingles vaccine. On an unknown date, the patient received Influenza vaccine Quadrivalent unspecified season. On 2nd February 2021, the patient received the 2nd dose of COVID 19 VACCINE. On 15th February 2021, between 2 and 4 months after receiving Shingles vaccine and less than 2 years after receiving Influenza vaccine Quadrivalent unspecified season, the patient experienced clot blood (serious criteria GSK medically significant). In February 2021, the patient experienced swelling of feet, ankle swelling, foot pain and pain ankle. The patient was treated with rivaroxaban (Xarelto). On an unknown date, the outcome of the clot blood was unknown and the outcome of the swelling of feet, ankle swelling, foot pain and pain ankle were recovering/resolving. It was unknown if the reporter considered the clot blood, swelling of feet, ankle swelling, foot pain and pain ankle to be related to Shingles vaccine and Influenza vaccine Quadrivalent unspecified season. Additional details were provided as follows: The reporter was the patient's son. The age at vaccination was not reported. The patient did not have medical history and family history. The patient got the Flu vaccine every year. The patient received 2nd dose of Covid vaccine in left arm. The reporter did not have NDC, lot and expiry date for the patient's 1st and 2nd Covid vaccine. The patient was told by the nurse administering the Covid vaccine that the 2nd dose would be a little bit stronger. Either on 04th February 2021 or 05th February 2021, less than a week after receiving Covid vaccine, less than 4 months after receiving Shingles vaccine and less than 2 years after receiving Flu vaccine, the patient experienced severe swelling and pain in foot, ankle and calf. The patient first noticed left foot was swollen. The patient stated her foot was sore. The reporter did not know if it went to her ankle and then from there. Doctor advised the patient the patient had a clot and was put on Xarelto. An angiography and catheter were suggested to see if she had something closing in her. The patient would be going back in few weeks to see about the clot. The patient had never had this clotting concern before. Reporter clarified that, the patient was going to have another procedure such as angiography or catheter, but the patient had an MRI on 15th February 2021, 13 days after receiving Covid vaccine, and was diagnosed with the clot. The patient spoke with doctor who decided to put the patient on Xarelto. No information of NDC, lot and expiry date or dosing of Xarelto was provided. The reporter thought the patient's clot was weird and odd. At the time of reporting, the pain and swelling were gotten better. No further details were provided. The reporter consented to follow up. It was unknown if the reporter considered the clot blood, swelling of feet, ankle swelling, foot pain and pain ankle to be related to Covid vaccine.</p>
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COVID19 VACCINE	JANSSEN	1157508-1	65+ years	Unknown	<p>HYPOCHROMIA; HIGH WHITE BLOOD CELLS; DVT WITH INFLAMMATION AND SWELLING OF RIGHT LOWER LEG; RUNNY NOSE; BILATERAL WATERY EYES; LEFT ARM TENDERNESS POST IMMUNIZATION; URINARY TRACT INFECTION; LOWER BACK PAIN; This spontaneous report received from a patient concerned a 68-year-old female. The patient's height, and weight were not reported. The patient's concurrent conditions included baker's cyst, and reflux sympathetic dystrophy. The patient experienced drug allergy when treated with gabapentin, and prednisone, drug intolerance when treated with codeine, and ibuprofen. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805031, expiry: UNKNOWN) once a total dose was not reported, administered on 10-MAR-2021 at right arm for prophylactic vaccination. No concomitant medications were reported. On MAR-2021, the subject experienced urinary tract infection. On MAR-2021, the subject experienced lower back pain. On 10-MAR-2021, the subject experienced left arm tenderness post immunization. On 11-MAR-2021, the subject experienced runny nose. On 11-MAR-2021, the subject experienced bilateral watery eyes. On 14-MAR-2021, the subject experienced deep vein thrombosis with inflammation and swelling of right lower leg. On 23-MAR-2021, Laboratory data included: Diagnostic ultrasound (NR: not provided) confirmed DVT right lower leg, Urinalysis (NR: not provided) Unknown, and White blood cell count high (NR: not provided) 10.35 increased and was previously 9.23 not reported. Treatment medications included: ciprofloxacin for urinary tract infection. On 24-MAR-2021, the subject experienced hypochromia. On 24-MAR-2021, the subject experienced high white blood cells. Additional treatment medications (dates unspecified) included: rivaroxaban for deep vein thrombosis. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from runny nose, and bilateral watery eyes on 12-MAR-2021, and left arm tenderness post immunization on 11-MAR-2021, had not recovered from deep vein thrombosis with inflammation and swelling of right lower leg, high white blood cells, and hypochromia, and the outcome of urinary tract infection and lower back pain was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0 20210348648-Covid-19 vaccine ad26.cov2.s-Deep vein thrombosis. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>
COVID19 VACCINE	JANSSEN	1157533-1	Unknown	Unknown	<p>DIZZINESS; FELL; HURT HIMSELF; SOME DAMAGE TO HIS KIDNEYS IN THE PROCESS (BLOOD CLOT); SOME DAMAGE TO HIS KIDNEYS IN THE PROCESS (BLOOD CLOT); CONFIRMED COVID-19 POSITIVE; This spontaneous report received from a patient via a company representative concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 11-MAR-2021 for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 15-MAR-2021, the patient became ill with COVID like symptoms, and got tested for COVID on 22-Mar-2021 and received results that he was COVID positive on 25-Mar-2021 and was running high temperatures (fevers over 103), On 27-MAR-2021, the patient became dizzy, fell and hurt himself, was rushed to the hospital and was admitted same day. He did some damage to his kidneys in the process. On 25-MAR-2021, Laboratory data included: COVID-19 virus test positive (NR: not provided) Positive. On 25-MAR-2021, Laboratory data included: Body temperature (NR: not provided) Over 103. Laboratory data included: Oxygen consumption decreased (NR: not provided) 87. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the confirmed covid-19 positive, dizziness, fell, injury to kidney, hurt himself and blood clot was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition) This report was associated with product quality complaint : 90000174591.; Sender's Comments: V0: 20210355610- Covid-19 Vaccine Ad26.Cov2.S-Confirmed Covid-19 Positive. This event is considered Unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event. 20210355610- Covid-19 Vaccine Ad26.Cov2.S - Dizziness, Fell, Hurt himself, Some damage to his kidneys in the process (blood clot). This events are considered Unassessable. The events have a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the events.</p>

COVID19 VACCINE	JANSEN	1165571-1	Unknown	Unknown	PULMONARY EMBOLISM AFTER VACCINATION; This spontaneous report received from a pharmacist concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 12-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On evening 15-MAR-2021, the patient experienced pulmonary embolism after vaccination, and was hospitalized (date unspecified). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of pulmonary embolism after vaccination was not reported. Vaccination anatomical approach site is unknown. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0-20210331460-pulmonary embolism. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.
COVID19 VACCINE	JANSEN	1168970-1	65+ years	Unknown	ATRIAL FIBRILLATION; INABILITY TO SWALLOW; BLOOD CLOT IN RIGHT ARM; LOW BLOOD PRESSURE; DEATH 4 DAYS AFTER RECEIVING VACCINE; This spontaneous report received from a vaccine facility via a company representative concerned a 95-year-old female. The patient's height, and weight were not reported. The patient's concurrent conditions included atrial fibrillation. The patient received COVID-19 VACCINE AD26.COV2.S (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 2021 for prophylactic vaccination. No concomitant medications were reported. The batch number was not reported and has been requested. It was reported that on an unspecified date in 2021 the patient received Janssen Covid-19 Vaccine and within 6hrs she had a major atrial fibrillation episode, then several the following day. The next day, she lost her ability to swallow. Two days later she was on oxygen. Three days later she developed a blood clot in her right arm, was still on oxygen and blood pressure was falling. On an unspecified date, the patient died 4 days after receiving vaccine. The action taken with COVID-19 VACCINE AD26.COV2.S was not applicable. The patient died 4 days after receiving vaccine on an unspecified date, and the outcome of atrial fibrillation, inability to swallow, blood clot in right arm and low blood pressure was not reported. This report was serious (Death, Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: 20210400509: This spontaneous report received from a vaccine facility via a company representative involved a 95-year-old female with the past medical history remarkable for atrial fibrillation who received the Janssen COVID-19 Vaccine for prevention of COVID-19 infection and within 6hrs had a major atrial fibrillation episode. No concomitant medications were reported. The next day, she lost her ability to swallow. Two days later she was on oxygen. Three days later she developed a blood clot in her right arm, was still on oxygen and blood pressure was falling. On an unspecified date, the patient died 4 days after receiving vaccine. No information was provided regarding the cause of death. Considering the patient's past medical history of atrial fibrillation, the causality for the event of atrial fibrillation, as well the consequent events is assessed not related to the Janssen COVID-19 Vaccine.; Reported Cause(s) of Death: DEATH 4 DAYS AFTER RECEIVING VACCINE
COVID19 VACCINE	JANSEN	1176466-1	50-59 years	Unknown	PE; DVT; This spontaneous report received from a physician via a company representative concerned a 53 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included family history of DVT, and family history of PE. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On unspecified date in 2021, the patient experienced PE (pulmonary embolism) and DVT (deep vein thrombosis). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the PE and DVT was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: 20210332653-Covid-19 Vaccine AD26.COV2.S-PE and DVT. This event(s) is considered not related. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY
COVID19 VACCINE	JANSEN	1190365-1	Unknown	Unknown	Urine bleeding at the day of injection. Heavier period, nose bleeding, and fatigue

COVID19 VACCINE	JANSSEN	1202608-1	60-64 years	Unknown	started coughing on 03/27/2021 and was taking to hospital on 03/30/2021. There he was treated for blood clots with anticoagulants and a filter placed in the vena cava.
COVID19 VACCINE	JANSSEN	1203128-1	Unknown	Unknown	DVT; PULMONARY EMBOLISM; KIDNEY BLEEDING; This spontaneous report was received from a physician, and concerned an adult male patient (greater than 50 years old). Initial report was processed along with additional information received on 12-APR-2021. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine AD26.Cov2.S (suspension for injection, intramuscular, batch number was not reported) dose and site of vaccination were not reported, administered on 20-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On an unspecified date in 2021, the patient experienced deep vein thrombosis (DVT), pulmonary embolism (PE), and kidney bleeding. The patient was admitted to the hospital and was treated with heparin as well as an inferior vena cava (IVC) filter (put in after he experienced bleeding from his kidney). Laboratory data included: a negative COVID-19 virus test, and throughout hospitalization his platelet count (NR: not provided) was normal: 191,000 and 264,000 (units not provided). The patient's test came back positive for one copy of the Factor V Leiden mutation which predisposed him to blood clots. On 12-APR-2021, the patient was to start a trial to Lovenox (enoxaparin sodium); they will assure there is no bleeding, prior to discharge. At the time of this report, the patient was still hospitalized but doing well. Action taken with Covid-19 vaccine AD26.Cov2.S was not applicable. The patient was recovering from DVT, pulmonary embolism, and kidney bleeding. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: v0 An adult (greater than 50 years old) male patient with a past medical history remarkable for the Factor V Leiden mutation experienced deep vein thrombosis, pulmonary embolism, and kidney bleeding on an unspecified date after receiving Janssen COVID-19 Vaccine Ad26.COVID.S. The patient was admitted to the hospital and was treated with heparin as well as an inferior vena cava (IVC) filter (put in after he experienced bleeding from his kidney). The patient had a negative COVID-19 virus test, and throughout hospitalization his platelet count was normal: 191,000 and 264,000 (units not provided). The Factor V Leiden mutation is known to predispose patients to venous thrombosis, therefore the causality for deep vein thrombosis, pulmonary embolism as well as a consequent kidney bleeding most likely due to heparin treatment is assessed not related to the vaccination.
COVID19 VACCINE	JANSSEN	1205474-1	65+ years	Unknown	She fell twice. The second time was due to a blood clot on the brain that led to multiple bleeds under dura and the brain. She needed an emergency craniotomy and is now undergoing acute rehab for speech, PT and OT.
COVID19 VACCINE	JANSSEN	1213393-1	Unknown	Unknown	Lost consciousness and speech, blood clot to the brain caused a stroke
COVID19 VACCINE	JANSSEN	1215569-1	30-39 years	Unknown	Pt presented w/ chest pain, pulmonary embolism confirmed via CTA Chest on 4/15/2021 1 week after J&J vaccination (4/7). Also tested positive covid on 4/15. Being treated with heparin infusion

COVID19 VACCINE	JANSSEN	1217069-1	65+ years	Unknown	<p>DVT (LEFT CALF); PULMONARY EMBOLISM (BOTH LUNGS); ATRIAL FIBRILLATION; BLOOD CLOT IN RIGHT VENTRICLE; This spontaneous report was received from a consumer (patient's wife) and concerned a 68 year old male. The patient's weight was 250 pounds and was obese (body mass index 40) and sedentary. His height was not provided. The patient's concurrent conditions included high blood pressure, and 2 gout attacks in the last 8 months. The last gout attack was 2 weeks ago in the left foot. There was no history of clots or atrial fibrillation. He had a strong family history of thrombosis: his father had 2 episodes of deep vein thrombosis and his mother had a pulmonary embolism. No testing to identify any familial clotting issues have been performed. The patient developed a cough starting 29-MAR-2021 and, prior to vaccination, took a COVID-19 test on 31-MAR-2021 which was negative. On 02-APR-2021 a rapid COVID-19 test also came back negative. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 043A21A, and expiry: UNKNOWN) on 02-APR-2021 at approximately 19:00 in the left arm for prophylactic vaccination. Concomitant medications included amlodipine, hydrochlorothiazide, and losartan for high blood pressure. On 03-APR-2021, the patient's cough persisted but had not worsened and he developed pain in the ribs on the right. His wife checked his pulse, which seemed fast and irregular. His respiratory rate was 22 breaths per minute and his oxygen saturation with a home pulse oximeter was in the 70s. He was not in distress at the time. The patient called his physician and the doctor suggested to go to Emergency room. The patient went to Emergency room at approximately 10:00. An echocardiogram revealed a number of clots in the right ventricle which were ""bouncing all around"". He was also found to be in atrial fibrillation which the doctors said was secondary to the ventricular clots. Unspecified tests revealed a saddle pulmonary embolus and a deep vein thrombosis on the left. He was diagnosed with deep vein thrombosis (left calf), pulmonary embolism (both lungs), blood clots in right ventricle and atrial fibrillation. Platelet count was not known by the reporter; it is unknown if D-dimer and fibrinogen levels were performed. He underwent emergency surgery at 19:00, during which most of the ventricular clots and the pulmonary embolism were removed. He was placed on heparin after the surgery. He spent 5 days in the Intensive Care Unit (ICU) and 2 additional days in the hospital. The patient was discharged from the hospital after 1 week and had recovered from the events of deep vein thrombosis (left calf), pulmonary embolism (both lungs), atrial fibrillation, and blood clots in right ventricle. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The reporter did not believe that the covid-19 vaccine ad26.cov2.s had caused deep vein thrombosis (left calf), pulmonary embolism (both lungs), atrial fibrillation, and blood clot in right ventricle This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: a 68-year-old male experienced left deep vein thrombosis, saddle pulmonary embolism, right ventricular thrombosis, and atrial fibrillation, approximately 15 hours after receiving the Janssen COVID-19 vaccine for prevention of COVID-19 infection. The patient has a history of hypertension, is obese (BMI 40) and has a strong family history of blood clots. He tested negative for COVID 2 days before and the day of vaccine administration. He developed a cough 4 days prior to vaccination. The morning after vaccination, he</p>
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COVID19 VACCINE	JANSSEN	1217752-1	Unknown	Unknown	<p>SHORTNESS OF BREATH; CHEST PAIN; SEVERE BLOOD CLOTS; This spontaneous report was received from a female patient of unspecified age. The patient's weight, height and medical history were not reported. The patient received COVID-19 vaccine Ad26.CoV2.S (suspension for injection, route of administration not reported), dose not reported, on 29-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, within a week of receiving the vaccine, the patient reported that she began experiencing shortness of breath and increasing chest pain. On 11-APR-2021, the patient was admitted to the hospital and a diagnosis of severe blood clots was made. After a full work-up, no etiology was determined. The action taken with COVID-19 vaccine Ad26.CoV2.S was not applicable. The outcomes of the shortness of breath, chest pain and severe blood clots were not reported. This report was serious (caused hospitalization).; Sender's Comments: V0:This female patient of unspecified age was hospitalized due to shortness of breath and increasing chest pain an unspecified time after blinded COVID-19 VACCINE Ad26.COVID2.S was administered intramuscularly for prevention of symptomatic SAR-CoV-2 virus infection. No concomitant medications, past medical history has been reported. On an unspecified date, within a week of receiving the vaccine, the patient reported that she began experiencing shortness of breath and increasing chest pain. the patient was admitted to the hospital and a diagnosis of severe blood clots was made. After a full work-up, no etiology was determined. At the time of the report the outcome of the event is unknown. Based on the limited information the event is inconsistent with the causal association to immunization, per the WHO causality classification for adverse events following immunization. The event is considered not related to the blinded study vaccine. Additional information has been requested for further assessment.</p>
COVID19 VACCINE	JANSSEN	1218182-1	30-39 years	Unknown	<p>Asthma flair up, abdominal pain, blood clot, headache, and lack of sleep.</p>
COVID19 VACCINE	JANSSEN	1218531-1	Unknown	Unknown	<p>DEEP VEIN THROMBOSIS; This spontaneous report received from a patient concerned a 46 year old male. Initial information was received and processed with additional information received on 15-APR-2021. The patient's weight and height were not reported. Patient's medical history included insomnia for which he took klonopin occasionally. Patient was non-smoker. Patient's body fat was reported as 6% The patient received vaccination with Janssen COVID-19 VACCINE (covid-19 vaccine ad26.cov2.s) (suspension for injection, route of admin intramuscular, batch number: Unknown) dose was not reported, administered on 14-MAR-2021 13:00 in left arm for prophylactic vaccination. Batch number was not reported, will be requested. No concomitant medication was reported as patient reported not taking any medication at the time of the event. Patient' did not have any blood work done since taking the vaccine. On 23-FEB-2021, platelet count was 206. On 05-APR-2021, the patient was diagnosed with deep vein thrombosis. Patient reported that after 2 weeks of vaccination, he experienced pain in left calf muscle for 2-3 days. Physician sent the patient for doppler scan for his leg. Patient was diagnosed with deep vein thrombosis. Treatment medications included: Eliquis (apixaban). Patient was prescribed apixaban 20 mg a day for a week and continue with it 10 mg a day for 2.5 months. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of deep vein thrombosis was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: A 46-year-old man was diagnosed with deep venous thrombosis (DVT) in his left leg 21 days after vaccine. There was no relevant medical history or concomitant medications, he is a nonsmoker, and there is no family history of thrombosis. Nineteen days before vaccine his platelet count was normal at 206,000 and no laboratory work has been performed since then. The patient was treated with Eliquis. Idiopathic DVTs often are followed by an extensive workup to identify the cause, and the patient is reaching out to his physician to discuss further. Based on information currently available, company causality is considered possibly related.</p>

COVID19 VACCINE	JANSSEN	1227128-1	Unknown	Unknown	<p>THREE BLOOD CLOTS IN THE LUNG; TWO BLOOD CLOTS IN THE LEG; HEART ENLARGEMENT OF LOWER CHAMBERS; This spontaneous report received from a consumer concerned an 86 year old female patient. Initial information received on 13-APR-2021 and processed with additional information received on 15-APR-2021. The patient's weight was 161 pounds, and height was 67 inches. The patient's past medical history included hip fracture in 2015, and uncomplicated hip replacement surgery in 2015. Patient's concurrent conditions included non-smoker and no alcohol use. No recent travel or trauma was reported. No varicose veins or known cancer was reported. Patient saw her doctor for annual checkups and cancer screening. She is an active person who lives alone, still drives, and performs activities of daily living independently. The patient received vaccination with covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029) dose was not reported, administered on 08-MAR-2021 for prophylactic vaccination. Vaccination site was not reported. No concomitant medications were reported as it was reported that the patient denied HRT and chronic medications. Approximately 1 week later, on or about 15-MAR-2021, she began to feel fatigue, tiredness, and shortness of breath which she thought might be due to the start of a heavy pollen season. On 11-APR-2021, the patient's fatigue, shortness of breath, and tiredness did not improve, so her son took her to the Emergency Room (ER), where CT scan found 3 clots in her lungs and duplex scan found 2 clots in her legs (patient's son was not certain if bilateral or unilateral). Patient's oxygen saturation was in 80s. On 11-APR-2021, a test also revealed that the lower chambers of her heart were enlarged. On 12-APR-2021, patient underwent EKOS procedure to treat lung clots. Tissue Plasminogen Activator (TPA) had been put into the lungs via EKOS procedure 'with ultrasound inserted into blood clot in the lung'. Patient initially was treated with heparin but was stopped. Patient was treated with unspecified anticoagulant as patient's son did not know. Pulse rate was 139. On 12-APR-2021, patient was admitted to Intensive Care Unit (ICU) (no beds were available on 11-APR-2021). He had no information regarding lab results. On 15-APR-2021, patient was transferred out of ICU to a room on regular floor. Patient was still very tired. Oxygen saturation was in 90s. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from three blood clots in the lung, two blood clots in the leg, and heart enlargement of lower chambers. This report was serious (Hospitalization Caused / Prolonged, and Life Threatening); Sender's Comments: V0: This 86 year-old active, independent female was hospitalized for 3 blood clots in her lungs and 2 blood clots in her legs 5 weeks after receiving Janssen Covid-19 vaccination. Medical history includes hip surgery after a hip fracture with uncomplicated course 6 years prior; she is a nonsmoker, does not have varicose veins, no known cancer, no history of recent trauma or travel and takes no chronic medications. Approximately 1 week after vaccination, the patient began to feel fatigue and shortness of breath. She initially thought her symptoms were due to the start of heavy pollen season. When symptoms did not improve 4 weeks later, she went to the emergency room where CT scan found 3 clots in her lungs and duplex scan found 2 clots in her legs. Oxygen saturation was in the 80s at that time. The following day she underwent EKOS procedure to treat the lung clots and was initially treated with heparin.</p>
COVID19 VACCINE	JANSSEN	1227129-1	Unknown	Unknown	<p>BLOOD CLOT; RIGHT LEG PAIN; HEADACHE; This spontaneous report received from a patient concerned a patient of unspecified age and sex. The patient's height, and weight were not reported. The patient's concurrent conditions included COVID-19. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805022, and expiry: UNKNOWN) dose was not reported, administered on 06-MAR-2021 at 02:19 for prophylactic vaccination. No concomitant medications were reported. The patient reported that she had a blood clot/pain in right leg 2-3 days after she received the vaccine. She reported that she used compression socks for a week. The patient also reported that she experienced headaches (date unspecified), which still come and go every other day. The patient stated that she had the same blood clot pain in the same leg as when she had COVID-19 infection in MAR-2020. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from headache, and the outcome of blood clot and right leg pain was not reported. This report was serious (Other Medically Important Condition); Sender's Comments: V0: A patient of unspecified age and sex reported a ""blood clot/pain"" in right leg 2-3 days after vaccine. The patient had a history of ""blood clot pain"" in the same leg when she had COVID infection one year ago. History of thrombosis would provide a plausible alternative explanation for the event, although there are insufficient details to make a meaningful medical assessment. The patient was contacted and could not be immediately reached. Additional information has been requested for further assessment.""</p>

COVID19 VACCINE	JANSSEN	1227130-1	Unknown	Unknown	<p>PNEUMONIA; BLOOD CLOTS; This spontaneous report received from a consumer concerned an 89 year old male. Initial information was received on 13-APR-2021 and processed with additional information received on 15-APR-2021. The patient's height, and weight were not reported. The patient's past medical history included congestive heart failure (ejection fraction 20%), large lower left groin hernia, atrial fibrillation, and dementia. No known drug allergies was reported. There was no history of blood clots. The patient received vaccination with covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: Unknown) dose was not reported, administered on 04-MAR-2021 for prophylactic vaccination. Vaccination site was not reported. Batch number was not reported, will be requested. Concomitant medications included apixaban twice a day for atrial fibrillation. On 11-MAR-2021, the patient was taken to Emergency Room (ER) and diagnosed with pneumonia. Patient was awake over 48 hours 'felt due to dementia and illness'. On 14-MAR-2021, the patient was taken back to hospital and X-ray and CAT scan showed saddle pulmonary embolism. On 15-MAR-2021, the patient was discharged to a home with hospice. On 23-MAR-2021, the patient deceased. It was unknown if autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death, Hospitalization Caused / Prolonged); Sender's Comments: V0: An 89-year old man experienced fatal saddle pulmonary embolism 10 days after vaccine. Relevant medical history included congestive heart failure with ejection fraction 20%, atrial fibrillation (A Fib), and dementia. Relevant concomitant medication (others not reported) included Eliquis for A fib. The patient was diagnosed with pneumonia in the Emergency Department 7 days after vaccine, and 3 days later was brought back to the hospital and diagnosed with saddle pulmonary embolus. He was discharged home on hospice the next day and died 19 days after vaccine. There was no reported thrombocytopenia. The patient's age, concurrent pneumonia, and complicated past medical history are confounders. There is insufficient information to make a meaningful medical assessment. Additional information has been requested, including attempts to contact the patient's treating physicians.; Reported Cause(s) of Death: PNEUMONIA; BLOOD CLOTS</p>
COVID19 VACCINE	JANSSEN	1227818-1	Unknown	Unknown	<p>BLOOD CLOT; This spontaneous report received from a consumer via media by a company representative concerned a female of unspecified age. The patient's height, and weight were not reported. The patient was prone to blood clots her entire life, but managed it. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration and batch number were not reported) dose (1 total), start therapy date were not reported, for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient developed a blood clot. A day after the vaccination, the patient died from the blood clot. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death, and Other Medically Important Condition); Sender's Comments: This anecdotal report from media involves a female patient of unspecified age who was prone to blood clots her entire life and on an unspecified date developed a blood clot and died from the blood clot a day after received the Janssen COVID-19 Vaccine Ad26.COV2. Concomitant medications, and details of the event were not reported. This case has insufficient information to make a meaningful medical assessment. The case will be assessed further when additional information is received.; Reported Cause(s) of Death: BLOOD CLOT</p>

COVID19 VACCINE	JANSSEN	1227819-1	50-59 years	Unknown	<p>BLOOD CLOT IN LEFT THIGH; SWELLING; FATIGUE; This spontaneous report received from a consumer concerned a 55 year old female. Initial information received on 13-APR-2021, processed along with information received via telephone communication on 15-APR-2021. The patient's weight was 100 pounds, and height was 152.4 centimeters. The patient's concurrent conditions included progressive multiple sclerosis, swelling of the left leg and foot, and non smoker, and other pre-existing medical conditions included the patient had no known drug allergies. the patient was not a pregnant at the time of reporting. The patient had no family history of thrombosis, no prior deep vein thrombosis (DVT). The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808609, expiry: UNKNOWN) dose was not reported, 1 total, administered on 22-MAR-2021 for prophylactic vaccination. Concomitant medications included badofen, escitalopram oxalate, and risedronate sodium (received 2 doses and stopped after the event). The patient's husband reported that in MAR-2021, the patient had symptoms of fatigue. On 23-MAR-2021, the patient had swelling and fatigue. Her fatigue was resolved on 24-MAR-2021 and swelling was resolving. On 05-APR-2021, the patient developed left thigh swelling. On 06-APR-2021, the patient's swelling was not going down and she visited her primary care physician. The physician could not determine the cause of swelling (left thigh very noticeable clot swollen around where clot was located) and the physician suspected clot and performed an AD dimer (fibrin degradation) test to look for potential blood clotting. The patient also had a venous duplex ultrasound that showed left leg clot. At 19:00 on the same day, the patient's physician advised to visit emergency room and determined there was a clot on left thigh and she was prescribed Eliquis Starter Pack (apixaban) for 3 months treatment and recommended another scan in several months. On 06-APR-2021, the patient's vitals were reported as blood pressure 124/70 mmHg, heart rate 88 bpm and oxygen saturation of 99%. Laboratory data included prothrombin time (PT) 13.4 sec, International normalized ratio (INR) 1.2 and activated partial thromboplastin time (APTT) 34.8 sec. (Normal range not reported for all) d-dimer and platelet count results were not available and Covid-19 test was not performed. Body max index was 19.5 kg/m2. On an unspecified date the patient was feeling better but had not recovered from the event. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fatigue on 24-MAR-2021, had not recovered from blood clot in left thigh, and recovering from swelling. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This case concerns a 55-year-old female subject, immobile due to progressive multiple sclerosis who developed a left thigh swelling 12 days after Janssen COVID-19 vaccine was administered intramuscularly for the prevention of symptomatic SARS-CoV-2 virus infection. The patient's concurrent conditions included body max index of 19.5 kg/m2, progressive multiple sclerosis and swelling of the left leg and foot. She is a non-smoker, no known drug allergies, no family history of thrombosis, or prior deep vein thrombosis (DVT). Symptoms started with swelling of the left thigh and fatigue. The fatigue resolved the next day. The patient's swelling in the left thigh was not going down and she visited her primary care physician who checked her D-dimer dimer (level not known to patient) and scheduled a venous duplex ultrasound that</p>
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COVID19 VACCINE	JANSSSEN	1227915-1	50-59 years	Unknown	<p>PULMONARY EMBOLISM; FEVER; SLIGHT COUGH; FEELING ACHY; CHILLS; This spontaneous report received from a patient concerned a 57 year old female. The patient's height, and weight were not reported. The patient's past medical history included right leg deep vein thrombosis (2011), arthroscopic meniscus surgery (2011), and superficial thrombophlebitis on left leg from mid-calf up to mid-thigh (AUG-2020), and concurrent conditions included factor V Leiden mutation. (2011). The patient was not on oral contraceptive pills. No immediate family had history of clots. A family member on mom's side has had clots. She had right leg deep vein thrombosis in 2011 after arthroscopic meniscus surgery on right knee, followed by long car ride. She was diagnosed with Factor V Leiden mutation in 2011 at the time of that clot. She was on warfarin for about 4 months then taken off. She did well for almost a decade. In last AUG-2020 had a superficial thrombophlebitis in left leg from mid-calf up to mid-thigh. She was Xarelto (rivaroxaban), monitored with ultrasound, taken off on 15/17-JAN-2021. The patient was previously treated with warfarin for right leg deep vein thrombosis, and rivaroxaban for superficial thrombophlebitis on left leg from mid-calf up to mid-thigh. The patient received COVID-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808980), administered on 30-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 30-MAR-2021, the patient felt good with slight cough on the day. She experienced achy by 7 PM, went to bed, then started getting the chills. At 2 AM on 31-MAR-2021 she had fever of 102 F. The laboratory appointment on Thursday, 01-APR-2021 unrelated laboratory was ordered. On 01-APR-2021, she was walking from parking lot to a building and was very short of breath. On 03-APR-2021, she was going up one flight of stairs, and felt severely short of breath and had dry cough. On 4-APR-2021, she experienced pain between shoulder blades in back. Oxygen saturation at home was 93-94% on RA while resting. On 4-APR-2021, she went to emergency room at a computerized tomogram (CT) of chest with contrast around at 6:30 PM showed massive pulmonary embolism. The right chamber the heart was enlarged due to the blockage from the embolism. Blood levels for ""stress on heart"" came back high. The patient went to cath lab for pulmonary angiogram on 4-APR-2021 and had EKOS catheter direct thrombolysis. She was started on heparin and transitioned to Xarelto (rivaroxaban) on 5-APR-2021. She was on blood thinners and the left lung was cleaned up and removed. The clot was still on the right lung, unable may or may not be cleared. The patient was discharged on 06-APR-2021. The patient was hospitalized for 2 days. On 04-APR-2021, Platelet count was 181 (normal range 140-440), on 5-APR-2021, Platelet count was 160 (normal range 140-440), on 6-APR-2021 Platelet count was 154 (normal range 140-440). At the time of this massive PE event, the patient was not on any anticoagulation and since the event, had been restarted on Xarelto, and she was told she needs to continue for life. The action taken with COVID-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from pulmonary embolism, and the outcome of feeling achy, chills, fever and slight cough was not reported. This report was serious (Hospitalization Caused / Prolonged, and Life Threatening).; Sender's Comments: V0: A 57-year-old woman with a history of Factor V Leiden deficiency (off anticoagulation for several months) and previous DVT 10 years ago was hospitalized for pulmonary embolism four days after</p>
COVID19 VACCINE	JANSSSEN	1227916-1	Unknown	Unknown	<p>BLOOD CLOTS IN BRAIN; This spontaneous report was received concerning a female patient of unspecified age. The patient's weight, height, and medical history were not reported. The patient received COVID-19 VACCINE AD26.COV2.S (suspension for injection, route of administration not reported), administered on an unspecified date in MAR-2021. The batch number was not reported. No medical history or concomitant medications were reported. On an unspecified date in MAR-2021, the patient was ill for a few weeks with a headache and was subsequently hospitalized with blood clots in her brain. The outcome of blood clots in brain was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: 20210425372 V0: This is a spontaneous report of a female of unspecified age who experienced a headache and reportedly blood clots in her brain (cerebral thrombosis), a few weeks after receipt of the Janssen COVID-19 vaccine. No medical history, concomitant medications or additional details were reported. No laboratory results were provided. Additional information has been requested. The blood clot could represent cerebral venous sinus thrombosis (to be clarified). The case will be assessed further when additional information is received.</p>

COVID19 VACCINE	JANSSEN	1227917-1	Unknown	Unknown	<p>BLOOD CLOT IN LEG; This spontaneous report received from a patient concerned a 72 year old male. The patient's height, and weight were not reported. The patient was reported to be over 6 feet tall and not overweight. The patient's past medical history included cataract surgery (in his 60s); and concurrent conditions included former smoker (ex-smoker who quit 1 year ago). The patient had no chronic medical conditions and had no history of recent travel or trauma. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unk) dose was not reported, administered on 01-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. The patient was not taking any concomitant medications. On 04-APR-2021, the patient's leg felt abnormal and on 05-APR-2021, the patient went to urgent care center, where an ultrasound found a blood clot. The patient was prescribed Eliquis (apixaban) and was since feeling better, however, still had leg discomfort. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from blood clot in leg. This report was serious (Other Medically Important Condition). Additional information was received from consumer (daughter of patient) via telephone follow up on 16-APR-2021. The following information was updated and incorporated into the case narrative: patient details, medical history, concurrent conditions, medical story including treatment, and event details.; Sender's Comments: V1: Follow up from the patient's daughter provided additional clinical details. This case concerns a 72 year-old male without significant medical history who was diagnosed with a blood clot in his leg 4 days after receiving the Janssen Covid-19 vaccine. He is not overweight, is not taking chronic medication, and had no recent trauma or travel. He quit smoking one year ago. Three days after vaccination, his leg felt abnormal. The following day, he went to an urgent care center where an ultrasound revealed a lower extremity blood clot. He was sent home with apixaban. No information regarding blood testing was provided. As of the time of the report (i.e. 11 days after his diagnosis), he is feeling better but still has leg discomfort. Based on the limited information, the relationship with Janssen Covid-19 vaccine is considered inconsistent. Additional information is being sought.</p>
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COVID19 VACCINE	JANSSEN	1227918-1	Unknown	Unknown	<p>DEEP VEIN THROMBOSIS OF LEFT PERONEAL VEIN; This spontaneous self-report was received from a patient, female 24 years of age. Initial information received from the patient on 13-APR-2021 was processed with additional information received from on 14-APR-2021 and from the patient via telephone follow up on 16-APR-2021. The patient's weight was 180 pounds, height 69 inches and BMI 26.6 kg/m2. Past medical history was insignificant with no prior history of blood clots, does not smoke, and does not use birth control. The patient was reportedly active and working as a teacher. Family medical history included clotting disorder (unspecified) on mother's side; mother does not have clotting disorder. In DEC-2020, COVID-19 test was negative. The patient received COVID-19 VACCINE AD26.COV2.S (suspension for injection, route of administration and dose not reported, batch number: 1805018, expiry: unknown) administered on 13-MAR-2021 in left deltoid for prophylactic vaccination. No concomitant medications were taken. On 13-MAR-2021, the patient experienced deep vein thrombosis of left peroneal vein (also reported as 2 blood clots). The pain started the day after vaccination on 14-MAR-2021, and she thought it was muscle soreness. On 20-MAR-2021, her physician sent an order for ultrasound, and on 21-MAR-2021, the blood clot was confirmed (also reported as 2 blood clots), report not provided. Laboratory tests included Platelet count (NR: not provided) 316,000 (units not provided), White blood cell count (NR: not provided) 9.1 (units not provided), Red blood cell count (NR: not provided) 5.19 (units not provided), Hemoglobin (NR: not provided) 14.6 (units not provided), Hematocrit (NR: not provided) 41.9 (units not provided), Alanine aminotransferase (NR: not provided) 15 (units not provided) and Aspartate aminotransferase (NR: not provided) 15 (units not provided). Antiplatelet PF4 antibodies was not performed. The patient was prescribed XARELTO (rivaroxaban) for 6 months. At the time of the report, the patient was still in pain described as throbbing with some improvement with treatment and no redness. The patient agreed to send medical records. The patient considered the blood clots to be caused by the vaccine. The action taken with COVID-19 VACCINE AD26.COV2.S was not applicable. The patient had not recovered from deep vein thrombosis of left peroneal vein. The suspected product quality complaint number 90000176260 was evaluated and voided; based on the PQC evaluation/investigation performed, it was confirmed that no product quality complaint was identified within the report. This report was serious (Other Medically Important Condition); Sender's Comments: V0: The case concerns a 24-year-old overweight female patient (BMI 26.6 kg/m2) who developed deep vein thrombosis of left peroneal vein 7 days after Janssen COVID-19 vaccine was administered intramuscularly for the prevention of symptomatic SARS-CoV-2 virus infection. The subject does not report any significant medical history or prior history of blood clots. She is a teacher, does not smoke and is active. Her family history is significant for clotting disorder in maternal family, but her mother does not have it. She does not take any medication or birth control. Last COVID-19 test 3 months prior was negative. The pain in the left leg started on the day of vaccination and was thought to be a muscle soreness. A week later her medical doctor ordered a diagnostic ultrasound, and the blood clot was confirmed (report not provided). Platelet count was 316, 000, WBC 9.1, RBC 5.19, HGB 14.6, HCT 41.9, ALT 15, AST 15 (D-dimer, platelet PF4 antibodies not available). The patient</p>
COVID19 VACCINE	JANSSEN	1227919-1	Unknown	Unknown	<p>BLOOD CLOT IN LEG; BLOOD CLOT IN LUNG; This spontaneous self-report was received from a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029, expiry: unspecified) dose and therapy start date were not reported for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, 2 weeks after getting vaccination, the patient experienced blood clot in leg and blood clot in lung. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the thrombosis leg and thrombosis pulmonary was not reported. The patient also reported to VAERS (no reference number provided). This report was serious (Other Medically Important Condition); Sender's Comments: A patient of unspecified age and sex experienced thrombosis leg and thrombosis pulmonary 2 weeks after vaccine. No concomitant medications were reported. No additional history, diagnostics, treatment, or other information was reported. There is insufficient information to make a meaningful medical assessment. Additional information has been requested.</p>

COVID19 VACCINE	JANSSEN	1227921-1	Unknown	Unknown	<p>DVT; HEADACHE; UNCONTROLLED SHAKING; TROUBLE BREATHING; FEVER; This spontaneous report received from a company representative concerned a 29-year-old female. The company representative heard the information on the local news. The patient's height, and weight were not reported. The patient was taking estrogen-based birth control pills. The patient received COVID-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 19-MAR-2021 for prophylactic vaccination. Concomitant medications included estradiol for birth control. On an unspecified date in MAR-2021, one-week post-vaccination, patient developed uncontrolled shaking, had trouble breathing and fever. She went to the emergency room for her symptoms and was sent home (no time frame was reported). One week later, she developed swollen legs and couldn't walk, and she was diagnosed with a deep vein thrombosis (DVT). On an unspecified date she was hospitalized and admitted in the intensive care unit (ICU). Patient was out of the ICU on 11-APR-2021 (Sunday). Patient was still under treatment. It was also reported that patient had headache that persisted for 2 weeks. The report was from the local news and follow-up was not possible. The action taken with COVID-19 vaccine ad26.cov2.s was not applicable. The outcome of the uncontrolled shaking, trouble breathing, fever, headache and DVT was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition); Sender's Comments: V0: This is a spontaneous report of a 29-year-old female who developed a deep vein thrombosis two weeks after receipt of the Janssen COVID-19 vaccine. She also reported uncontrolled shaking, trouble breathing, and fever one week after vaccine administration, and a headache which had persisted for two weeks. No medical history was reported; she was taking estrogen-based birth control pills. Estrogen-based birth control pills place the patient at risk for thrombosis, but there are insufficient other details to make a meaningful medical assessment regarding the events in the case.</p>
COVID19 VACCINE	JANSSEN	1227922-1	Unknown	Unknown	<p>BLOOD CLOT; BROKE TAIL BONE; VACCINE EXPOSURE DURING PREGNANCY; This spontaneous pregnancy report was received from a pharmacist via a company representative, and concerned an approximately 40 year old female. The patient's height, weight, and medical history were not reported. The patient received Covid-19 vaccine Ad26.COVID.S (suspension for injection, route of administration not reported, batch number: unknown) dose and vaccination site were not reported, administered in 2021 for prophylactic vaccination. No concomitant medications were reported. In 2021, the patient experienced vaccine exposure during pregnancy. The date of the patient's last menstrual period and expected delivery date were not provided. In 2021, the patient experienced broke tail bone during labor and gave birth (live birth). On an unspecified date in 2021, the patient experienced a blood clot and died. It was noted that she was at high risk for clots because she was 4 weeks post partum (gravida 1, para 1). Action taken with Covid-19 vaccine Ad26.COVID.S was not applicable. The patient died of a blood clot and broke tail bone in 2021; the outcome of vaccine exposure during pregnancy was not reported. It was unspecified if an autopsy was performed. This report was serious (Death). This case, from the same reporter is linked to 20210430297.; Sender's Comments: V0: The case concerns a pregnant female subject around age of 40, who developed thrombosis, skeletal injury and exposure during pregnancy an unspecified time after Janssen COVID-19 vaccine was administered intramuscularly for prevention of symptomatic SARS-CoV-2 virus infection. The subject's past medical history, last menstrual period, estimated date of delivery and concomitant medications were not provided. Per the reporter (pharmacist) the patient was at a high risk for blood clots because she was 4 weeks post-partum. The patient broke her tail bone during the labor, gave a birth, and later died of a blood clot. No additional information was provided. It is not known whether the autopsy was performed. Given alternative explanation and risk factors of pregnancy, labor and skeletal injury (trauma) the event of thrombosis is considered inconsistent with the causal association to immunization, per the WHO causality classification for adverse events following immunization. Events of skeletal injury was result of an accident and therefore not considered related. Company causality for event of thrombosis is considered not related to Janssen COVID-19 vaccine (Level 4 -Insufficient information available to confirm a possible, probable or a definitive case of venous thrombosis, per the Brighton Collaboration case definition); Reported Cause(s) of Death: BLOOD CLOTS; BROKE TAIL BONE</p>

COVID19 VACCINE	JANSSEN	1227923-1	< 6 months	Unknown	<p>COLD SYMPTOMS; DECREASED PLATELET COUNT; SADDLE PULMONARY EMBOLUS; BLOOD CLOT IN RIGHT LEG; This spontaneous report was received from a physician, and concerned a 58 year-old male patient. Initial report was processed along with additional information received on 16-APR-2021. The patient's height was 76 inches, weight was 266 pounds, body mass index 32.4. The patient's concurrent conditions included hypertension, and non-smoker. The patient had no personal or family history of clotting disorders, no recent trauma or travel. He had an active lifestyle (an outdoorsman who cut his own firewood). The patient received Covid-19 vaccine Ad26.COVS.2.S (suspension for injection, route of admin not reported, batch/lot number: 1808609) dose was not reported, administered on 02-APR-2021 vaccine anatomical site unknown, for prophylactic vaccination. Concomitant medications included hydrochlorothiazide for hypertension. On 03-APR-2021, the patient experienced cold symptoms. It was reported that some days later, he developed shortness of breath, dyspnea on exertion, decreased exercise tolerance and right calf swelling. On 13-APR-2021, the patient went to the doctor's office for his symptoms. An electrocardiogram (EKG) was normal, and the ultrasound of right leg revealed a blood clot. As the patient preferred to keep costs down, he was not hospitalized and was started on anticoagulant Eliquis (apixaban). He was not hypoxic. On 14-APR-2021, he called the doctor after a syncopal episode and was advised to go to the emergency room (ER) where a computerized tomography (CT) scan showed a saddle pulmonary embolus with evidence of right heart strain. His oxygen (O2) saturation was 97-98%. No treatment was given in the ER as he already had started apixaban (2 doses received by that time). Laboratory data included a normal comprehensive metabolic profile, normal troponin, white blood cell count 9, hemoglobin 16, platelet count 120 (lower limit normal: 130). No other tests were performed, and no prior complete blood count (CBC) was available. On 16-APR-2021, the doctor called the patient for follow up, and noted that he was feeling better. Action taken with Covid-19 vaccine Ad26.COVS.2.S was not applicable. The outcome of the blood clot in right leg, saddle pulmonary embolus, decreased platelet count, and cold symptoms was not reported. This report was serious (Other Medically Important Condition); Sender's Comments: V0: This 58 year-old obese (BMI 32.4) male was diagnosed with a right leg blood clot and saddle pulmonary embolus 11 and 12 days, respectively after vaccination with the Janssen Covid-19 vaccine. Medical history included hypertension controlled with hydrochlorothiazide. He is a non-smoker who leads an active lifestyle; there was no recent trauma or travel and he had no personal or family history of clotting disorders. The day after the vaccination, he experienced cold symptoms. Then, an unspecified number of days later, he developed right calf swelling, shortness of breath, dyspnea on exertion, and decreased exercise tolerance. Eleven days after vaccination, he went to see his doctor who ordered an ultrasound which revealed a blood clot in his right leg. EKG was normal and he was not hypoxic. Apixaban was started as an outpatient. The following day, the patient called the doctor after a syncopal episode and was advised to go to the emergency room; CT scan revealed a saddle pulmonary embolus with evidence of right heart strain. Oxygen saturation was 97-98%. Labs included normal comprehensive metabolic profile, troponin, white blood cell count of 9, hemoglobin 16, platelet count 120 (lower limit normal: 130). No</p>
COVID19 VACCINE	JANSSEN	1227924-1	40-49 years	Unknown	<p>SUPERFICIAL THROMBOPHLEBITIS; This spontaneous report received from a patient and concerned a 40 year old white, not Hispanic or Latino female. The patient's height, and weight were not reported. The patient's concurrent conditions included varicose veins. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, frequency 1 total administered on 17-MAR-2021 to Left deltoid in arm for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 30-MAR-2021 and on 31-MAR-2021, the patient experienced severe leg pain on right side. Patient tried hot and cold compress. The patient wore compression stockings but nothing helped. Patient went to doctor on 13-APR-2021 and doctor diagnosed Superficial thrombophlebitis. The patient planned to get ultrasound on 14-APR-2021, next day, at 6 pm. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from superficial thrombophlebitis. This report was serious (Other Medically Important Condition); Sender's Comments: V0: A 40-year-old woman with a history of varicose veins experienced superficial thrombophlebitis 13 days after vaccine. An ultrasound was planned to confirm the diagnosis. Varicose veins provide a plausible alternate risk factor for the event. However, there is insufficient information to make a meaningful medical assessment. Additional information has been requested, including the ultrasound report.</p>

COVID19 VACCINE	JANSSEN	1227925-1	Unknown	Unknown	SUSPECTED PULMONARY EMBOLISM; THROMBOCYTOPENIA; This spontaneous report received from a health care professional from a state immunization program concerned a 60 year old male. The patient's height, and weight were not reported. The patient's past medical history included cancer, and concurrent conditions included overall poor health. The patient received COVID-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown), date of administration was not reported, for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, approximately 24 hours post-vaccination, the patient was taken to the hospital after being found unresponsive. It was suspected that the patient had experienced a pulmonary embolism, resulting in his death. Laboratory results revealed thrombocytopenia. Reportedly, no heparin was used in his treatment. On an unspecified date, the subject died from suspected pulmonary embolism, and had not recovered from thrombocytopenia. An autopsy had not been performed at the time of the report, as it was pending family's approval. The action taken with COVID-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death, and Other Medically Important Condition); Sender's Comments: VO: This is a spontaneous report of a 60-year-old male patient, who died of a suspected pulmonary embolism approximately 24 hours after receipt of the Janssen COVID-19 vaccine. The patient had an unspecified cancer and was described as in overall poor health. He was brought to a hospital, where it was suspected that he had died due to a pulmonary embolism. He was also found to be thrombocytopenic. The patient's cancer could provide a plausible alternative explanation for the event, although there are insufficient details to make a meaningful medical assessment at this time.; Reported Cause(s) of Death: SUSPECTED PULMONARY EMBOLISM
COVID19 VACCINE	JANSSEN	1227926-1	Unknown	Unknown	BLOOD CLOT; This spontaneous report received from a consumer via a company representative and concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, a week or so after the Covid-19 vaccination the patient passed away in his sleep. The patient had no underlying condition. An autopsy was performed on an unspecified date and the patient was found to have blood clot. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death); Sender's Comments: VO: A male patient of unspecified age passed away in his sleep an unspecified time after receiving the Janssen COVID-19 vaccine for prevention of COVID-19 infection. It stated that the patient had no underlying condition. A blood clot was found by autopsy; no further details are provided. There is insufficient information to make a meaningful medical assessment. Additional information is being sought.; Reported Cause(s) of Death: BLOOD CLOT; Autopsy-determined Cause(s) of Death: BLOOD CLOT
COVID19 VACCINE	JANSSEN	1227928-1	60-64 years	Unknown	POTENTIAL DEEP VEIN THROMBOSIS; SMALL BLOOD CLOT; ANKLE CALF BOTH SWOLLEN; This spontaneous self-report was received from a patient and concerned a 64 year old female. The patient's height and weight were not reported. The patient's concurrent conditions included no known allergies and smoker. Other relevant history included no alcohol intake, nor any drug abuse/illicit drug use. The patient received COVID-19 VACCINE AD26.COVID.S (suspension for injection, route of administration and dose not reported, batch number: 1805029, and expiry: unknown) administered on 14-MAR-2021 on the left arm for prophylactic vaccination. No concomitant medications were reported. On 17-MAR-2021, the patient had ""ankle calf both swollen"" indicating potential deep vein thrombosis. She went to hospital emergency room, and ""HCP confirmed small clot"". The action taken with COVID-19 VACCINE AD26.COVID.S was not applicable. The patient was recovering from ""ankle calf both swollen"" and had not recovered from potential deep vein thrombosis and small blood clot. This report was serious (Other Medically Important Condition); Sender's Comments: VO: This is a spontaneous report of a 64 year old female who developed a swollen calf and ankle swelling indicating a potential deep vein thrombosis 3 days after receipt of Janssen COVID 19 vaccine. Patient was seen in the emergency room by HCP, who confirmed a small clot. No other medical history was reported but patient was noted to be a smoker, reported as 2x a year. Age increases the risk of deep vein thrombosis, but there is insufficient other details to make a meaningful medical assessment.""

COVID19 VACCINE	JANSSEN	1227930-1	Unknown	Unknown	<p>BLOOD CLOT; ARM SORENESS; TIREDNESS; This spontaneous report received from a patient and concerned a 36 year old female. The patient's weight was 177 pounds and height was 165 centimeters. The patient's past medical history included fibroid surgery (fibroid was taken out 2 months), and concurrent conditions included alcohol drinker (once a week - occasionally), non-smoker, no drug abuse or illicit drug use, no known allergies. The patient received COVID-19 vaccine ad26.cov2.s (suspension for injection, intramuscular (right deltoid), batch number: 043A21A) dose was not reported, administered on 05-APR-2021 for prevention of covid-19 disease. No concomitant medications were reported. On 05-APR-2021, an unspecified amount of time after vaccination, the patient experienced arm soreness and tiredness that resolved within 3 days. On 15-APR-2021, 10 days after vaccination, the patient experienced calf pain and blood clot. It was reported the patient felt a very sharp pain on her right calf while walking, pain scale was 8/10, and it was so painful that she could not put pressure on it. Therefore, she decided to go to the hospital to have it checked. Her attending physician confirmed based on ultrasound that she has a blood clot on her right leg. She was prescribed blood thinner Eliquis (apixaban) however she was still undecided because her insurance denied to cover it and it was out of pocket. Once she returned home, she stated that the sharp pain was gone and it was just achy. After conversation with her physician, her physician postponed the medication for now because he wanted to make sure that her blood was not already thin before prescribing a blood thinner. She will go to the hospital again on 16-APR-2021 to see a hematologist for blood works and her physician advised her not to work until 20-APR-2021 as a preventive measure. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from arm soreness, and tiredness on 08-APR-2021 and had not recovered from blood clot. This report was serious (Other Medically Important Condition, and Life Threatening).;</p> <p>Sender's Comments: V0: a 36-year-old female experienced a blood clot in her right leg, 10 days after receiving the Janssen COVID-19 vaccine for prevention of COVID-19 infection. The patient is a non-smoker, her BMI is 34.5; she has no other relevant medical history and reported no concomitant medications. Ten days after receiving the vaccine, she felt a sharp pain, graded 8/10, in her right calf while walking. Ultrasound showed a blood clot on her right leg. She was prescribed Eliquis but did not fill the prescription and the pain subsided; she was to have further blood tests and see a physician the following day. Additional information is being sought.</p>
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COVID19 VACCINE	JANSSEN	1227932-1	50-59 years	Unknown	<p>BILATERAL DEEP VEIN THROMBOSIS TO LOWER EXTREMITIES; PULMONARY EMBOLISM IN BOTH LUNGS; BODY ACHE; CHILLS; This spontaneous report received from a consumer concerned a 54 year old female. The patient's weight was 190 pounds, and height was 66 inches. The patient's past medical history included cancer, and concurrent conditions included no alcohol use, and non-smoker, and other pre-existing medical conditions included the patient was not pregnant at the time of reporting. The patient had no known allergies and drug abuse/illegal drug usage. The patient received JANSSEN COVID-19 VACCINE (covid-19 vaccine ad26.cov2.s) (suspension for injection, route of admin intramuscular, batch number: 1805031, and expiry: not reported) dose was not reported, 1 total, administered in left arm on 05-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 03-MAR-2021, the patient experienced chills. On 06-MAR-2021, the patient experienced body ache. Since 09-APR-2021, patient started experiencing leg pain and was admitted to a hospital on 10-APR-2021. The patient was diagnosed with 2 deep vein thrombosis (DVTs) to the lower extremities with pulmonary embolism. The patient was on therapeutic Lovonox (enoxaparin sodium) and was prescribed Lovonox injection twice a day for 6 months. The patient had visited emergency room and hospitalized for 5 days. The patient was discharged from hospital on 13-APR-2021. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from body ache, and chills on 10-MAR-2021, and was recovering from bilateral deep vein thrombosis to lower extremities, and pulmonary embolism in both lungs. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: This 54-year-old obese female with BMI of 30.7 was hospitalized due to bilateral deep vein thrombosis (DVT) to lower extremities and pulmonary embolism (PE) in both lungs 35 days after receiving JANSSEN COVID-19 VACCINE (covid-19 vaccine ad26.cov2.s) in left arm for prophylactic vaccination. The patient's past medical history included cancer. The subject had chills 2 days prior to the vaccination and body ache 1 day post vaccination. The symptoms resolved 5 days post vaccination. She started experiencing bilateral leg pain 33 days post vaccination and chest pain 34 days post vaccination. The patient visited emergency room and was hospitalized. She was diagnosed with bilateral DVTs to the lower extremities and PE in both lungs. Details of the hospitalization were not reported. She was discharged after 5 days of hospitalization with prescription of enoxaparin injection twice a day for 6 months. The patient was recovering from bilateral DVT to lower extremities and PE in both lungs. Based on the available information, with risk factors of obesity and cancer, DVT and PE are assessed as indeterminate with causal association to immunization, per WHO causality classification for adverse events following immunization. Company causality is considered not related to JANSSEN COVID-19 VACCINE. Additional information has been requested for further assessment.</p>
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COVID19 VACCINE	JANSSEN	1227933-1	50-59 years	Unknown	<p>THROMBOSIS ARM; SHORTNESS OF BREATHE; ARM BURNING; ARM DISCOMFORT; SWOLLEN ARM; This spontaneous report received from a patient concerned a 59 year old of unspecified sex. The patient's height, and weight were not reported. The patient's past medical history included blood clots treated with Eliquis. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805020, and expiry: UNKNOWN) dose was not reported,1 total administered on 08-MAR-2021, left arm for prophylactic vaccination. No concomitant medications were reported. On 22-MAR-2021, two weeks after vaccination the patient experienced swollen arm and arm discomfort. On 29-MAR-2021, the patient experienced shortness of breathe and arm burning. On 30-MAR-2021, the patient experienced thrombosis arm. Laboratory data (dates unspecified) included: Scan (NR: not provided) Right Arm Occluded. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from swollen arm, and shortness of breathe, and had not recovered from thrombosis arm, arm discomfort, and arm burning. This report was serious (Other Medically Important Condition); Sender's Comments: V0: This 59-year-old of unspecified gender, currently on Eliquis for history of blood clots noted swelling of arm with discomfort and burning (described as ""like from a match"" ) as well as shortness of breath 14 days after receiving COVID-19 VACCINE AD26.COVID.S on left arm. Scan showed right arm was occluded. Treatment for the events was not reported; the patient is recovering from swelling of arm and shortness of breath; the patient have not recovered from thrombosis of arm and arm discomfort/burning. The event is confounded by the underlying history of blood clots that is being treated medically. However, the events are assessed as indeterminate with a causal association to immunization, per the causality classification for adverse events following immunization based on a lack of a definitive plausible biological mechanism. Considering temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information has been requested for further assessment. ""</p>
COVID19 VACCINE	JANSSEN	1227934-1	18-29 years	Unknown	<p>FEMORAL DEEP VEIN THROMBOSIS; This spontaneous report received from a physician concerned a 30-40 year old male. The patient's height, and weight were not reported. The patient's pre-existing medical conditions were unknown. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) dose was not reported, administered on 25-MAR-2021 for prophylactic vaccination. The batch number was not reported. the company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 14-APR-2021, approximately 20 days after the patient received vaccination, he experienced femoral deep vein thrombosis. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from femoral deep vein thrombosis. This report was serious (Other Medically Important Condition); Sender's Comments: V0: A 30-40 year-old man experienced femoral deep vein thrombosis approximately 20 days after vaccination. No past medical history or concomitant medications were reported. There were no details provided, including diagnostic workup. There is insufficient information to make a meaningful medical assessment.</p>

COVID19 VACCINE	JANSSEN	1227936-1	50-59 years	Unknown	<p>BLOOD CLOT; This spontaneous report received from a patient concerned a 50 year old female. The patient's weight, height, and medical history were not reported. The patient was not pregnant at the time of report. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 203A21A expiry: UNKNOWN) dose was not reported, administered on 08-APR-2021 19:18 at right arm for prophylactic vaccination. No concomitant medications were reported. On 10-APR-2021 at 02.30 patient experienced severe cramping on front and back of right leg; she was unable to stand and had to sit down on the floor. The patient then started feeling the left leg also cramp and was rushed to the hospital. At 02:45 was in the hospital and received intravenous morphine and laboratory tests (hemoglobin and metabolic panel - test results not provided). At 04:24 patient received intravenous Valium. That same day, 10-APR-2021 at 05:07 Sodium Chloride (NaCl 0.9%) was stopped and the patient was released from hospital. On 13-APR-2021 the patient received D-Dimer testing. She stated the levels were 0.95 (units unspecified) ""which was elevated compared to average 0.5"". Her doctor notified her not to fly anywhere and have an ultrasound. On 14-APR-20-21 ultrasound performed. Reports came back with no Deep vein thrombosis (DVT) but still blood clotting was present in unknown location. On 15-APR-20201 patient has requested another D-Dimer test with her physician. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Other Medically Important Condition); Sender's Comments: V0: This 50-year-old female patient was rushed to the hospital for severe cramping of right leg 2 days after receiving COVID-19 VACCINE AD26.COV2.S on right arm. Hemoglobin and metabolic panel was awaiting results; D-Dimer was reported to elevated at 0.95; and ultrasound showed no deep vein thrombosis but was told that there was still blood clotting in an unknown location. Additional work up is being done. The patient was treated with Valium and IV fluid and was released from the hospital. Based on the information that is available, the event is assessed as indeterminate with the causal association to immunization, per the WHO causality classification for adverse events following immunization based on a lack of a definitive plausible biological mechanism. Considering temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information has been requested for further assessment.""</p>
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COVID19 VACCINE	JANSSEN	1230869-1	30-39 years	Unknown	<p>BLOOD CLOTS IN LEFT LUNG, TIRED, FEVERISH, This spontaneous report received from a consumer concerned a 34 year old male. The patient's weight was 175 pounds, height was 67 inches and Body mass index (NR: not provided) 27.4. The patient's concurrent conditions included non smoker, no personal or family history of clotting disorders and no recent trauma or travel. The patient was active and ran for 30 mins every day. The patient received COVID-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: 043AZ1A or 043A21A) frequency one total, dose was not reported, administered on 05-APR-2021 at 10:15 hours in left arm for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 05-APR-2021 in the evening, the patient experienced ""normal side effects"", specifically tiredness and fever (temperature was not taken) and he took 2 Advil and went to bed. On 06-APR-2021 in the morning, he felt back to his normal baseline. On an unspecified date of APR-2021 (08-APR-2021 or 09-APR-2021), he felt pain and tightness in his chest and difficulty breathing. He noticed that he had to work harder to do his daily run. On 13-APR-2021, when the symptoms did not improve, he went to the emergency room. The patient had blood was taken (results not reported). A computerised tomography (CT) scan showed 2 blood clots in the left lung and duplex scans of both legs did not reveal a clot. A chest x-ray was done but results not provided. The patient's COVID-19 test was negative, and he was admitted to the hospital and treated with intravenous heparin. It was reported that no oxygen was given. On 14-APR-2021, he was discharged with Eliquis which he should continue for 6 months. On 16-APR-2021, the chest pain was gone, and his breathing was better in the morning but still difficult later in the day. The action taken with COVID-19 vaccine ad26.cov2.s was not applicable. The patient recovered from tired, and feverish, and was recovering from blood clots in left lung. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: This 34 year-old overweight male (BMI 27.4) was hospitalized for 2 blood clots in his left lung 8 days after receiving vaccination with Janssen Covid-19 vaccine. He had no chronic medical conditions, was a nonsmoker, no personal or family history of clotting disorders, no recent trauma or travel, and exercised every day. On the evening of his vaccination, he felt tired and fever (temperature not taken) and took 2 ibuprofen and went to bed. The following morning, he felt back to normal. Two or three days later, he felt pain/tightness in his chest and difficulty breathing; he found it more difficult to perform his daily exercise. Eight days after vaccination, when his symptoms did not improve, he went to the emergency department where a CT scan showed 2 blood clots in his left lung. Covid-19 testing and duplex scans of his legs were negative. Blood tests were performed but results were unknown. He was hospitalized for 1 night, treated with IV heparin, and discharged the following day with apixaban. As of the time of this report, the chest pain had resolved and breathing was improved in the morning but still difficult later in the day. Based on the limited information (e.g. absence of blood test results), the relationship with Janssen Covid-19 vaccine is considered indeterminant.""</p>
COVID19 VACCINE	JANSSEN	1236116-1	Unknown	Unknown	<p>IN ICU WITH CLOTS; This spontaneous report was received from social media via a company representative and concerned a male patient of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: Unknown) dose, start therapy date were not reported, for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient was hospitalized in the intensive care unit (ICU) with clots (date unspecified). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome for the event of clots was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: v0 This report involves a male patient of unspecified age who received the Janssen COVID-19 Vaccine Ad26.COV2 and, after an unspecified period of time, was hospitalized in the intensive care unit (ICU) with ""clots"" (site unspecified). Medical history, concomitant medications, and details of the event were not reported. This case has insufficient information to make a meaningful medical assessment. The case will be assessed further when additional information is received.""</p>

COVID19 VACCINE	JANSSEN	1236127-1	Unknown	Unknown	BLOOD CLOTS IN MY LEFT LUNG; GOT SERIOUSLY SICK; This spontaneous report received from a patient via a company representative and concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received Janssen COVID-19 Vaccine (ad26.cov2.s) (suspension for injection, intramuscular, batch number: Unknown) dose was not reported, administered on 20-MAR-2021 for prophylactic vaccination. The batch number was not reported, and has been requested. No concomitant medications were reported. On an unspecified date, the patient got seriously sick and was hospitalized for blood clots in left lung on unspecified date. Patient reported blood clots in left lung that caused to be hospitalized for two days. Patient reported being on blood thinners (unspecified) and oxygen. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the got seriously sick and blood clots in my left lung was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: A patient of unspecified age and sex experienced blood clots in the left lung an unspecified time after vaccine. The patient reported being on blood thinners and oxygen. No further details were provided. There is insufficient information to make a meaningful medical assessment. Additional information has been requested.
COVID19 VACCINE	JANSSEN	1236404-1	Unknown	Unknown	VENOUS THROMBOSIS; PAIN IN LEFT LEG; This spontaneous report received from a consumer concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 06-APR-2021 for prophylactic vaccination. Frequency was 1 total. Vaccination site was unspecified. No concomitant medications were reported. Batch number is not reported and has been requested. On 09-APR-2021, the patient experienced pain in left leg. On 16-APR-2021, he was diagnosed venous thrombosis, and he was hospitalized (date unspecified). Consumer told that currently patient was admitted when she called. Treatment to treat adverse event was not reported. Hospital name and address was not reported. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from venous thrombosis, and pain in left leg. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: This is a spontaneous report of a male of unspecified age who developed a venous thrombosis and was hospitalized 10 days after receiving the Janssen COVID-19 vaccine. No medical history, concomitant medications or additional details were reported. Additional information has been requested. The case will be assessed further when additional information is received.
COVID19 VACCINE	JANSSEN	1240565-1	Unknown	Unknown	BLOOD CLOT; This spontaneous report received from a male patient of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, frequency 1 total administered on MAR-2021(2weeks ago from date of reporting) for prophylactic vaccination.The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. The patient wanted to know about the blood clots with the JNJ shot and was thinking that he had a blood clot on 13-APR-2021. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: A consumer of unknown age or gender called company to inquire what is going on with blood clots after vaccine. The subject stated that he thinks he has a blood clot 2 weeks after vaccine, but did not provide details, did not see a doctor or have an any diagnosis, and refused to see a doctor despite encouragement. He did not share any contact information or other information stating he would ""wait for our lies to come out about clots."" This case is confounded by a lack of meaningful history, a lack of diagnosis, a lack of workup, and a lack of contact information for any follow up. A meaningful medical assessment can not be made.""

COVID19 VACCINE	JANSSEN	1240727-1	50-59 years	Unknown	TINGLING IN LEGS; CHILLS; FEVER; HEADACHE; LOWER LEG PAIN; This spontaneous report received from a patient concerned a 50 year old female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose was not reported, administered on 12-APR-2021 09:00 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 12-APR-2021, the subject experienced lower leg pain. Laboratory data included: Fever (NR: not provided) 101. Treatment medications included: ibuprofen. On 12-APR-2021 15:30, the subject experienced chills. On 12-APR-2021 15:30, the subject experienced fever. On 12-APR-2021 15:30, the subject experienced headache. On 13-APR-2021, Laboratory data included: DVT (NR: not provided) 1.46 H. On 14-APR-2021, the subject experienced tingling in legs. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from chills, and fever on 13-APR-2021, was recovering from lower leg pain, and had not recovered from headache, and tingling in legs. This report was non-serious.
COVID19 VACCINE	JANSSEN	1241054-1	Unknown	Unknown	BLOOD CLOT IN LEFT CALF; This spontaneous report received from a patient and concerned a female of unspecified age. The patient was called to obtain additional information on 21-APR-2021 and message was left on a voicemail. The patient's height, and weight were not reported. The patient has no family history of thrombosis. The patient does not have any underlying conditions. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) dose was not reported, administered on 13-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 14-APR-2021, the subject experienced blood clot in left calf. The patient noted that she did not have any underlying conditions or family history that may have made her more predisposed to this diagnosis. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clot in left calf. This report was serious (Other Medically Important Condition); Sender's Comments: V0: This spontaneous report concerns a female patient of unspecified age who experienced a blood clot one day after Janssen COVID-19 vaccine was administered for prevention of symptomatic SARS-CoV-2 virus infection. The patient's height, and weight were not reported. The patient has no family history of thrombosis and has not reported any underlying conditions. No concomitant medications were reported. The patient did not provide details related to the blood clot, except it was not resolved at the time of the report. Given lack of alternative explanation and temporal plausibility the event is considered possibly related to Janssen COVID-19 vaccine.
COVID19 VACCINE	JANSSEN	1241143-1	Unknown	Unknown	BLOOD CLOT; This spontaneous report received from a consumer via a company representative concerned a female (consumer's wife) of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported, for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient experienced blood clot. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Other Medically Important Condition); Sender's Comments: V0: This is a spontaneous report of a female patient of unspecified age, who developed a blood clot an unspecified time after receiving the Janssen COVID-19 vaccine. No medical history or concomitant medications were provided. There is insufficient information to make a meaningful medical assessment. Additional information is being sought.

COVID19 VACCINE	JANSSEN	1241185-1	Unknown	Unknown	<p>BLOOD CLOT IN LEFT LEG; LEFT LEG CALF PAIN; This spontaneous report received from a patient concerned a 78 year old Asian, Not Hispanic or Latino male. The patient's weight was 220 pounds, and height was 67 inches. The patient's past medical history included stent (unknown where stent was placed), and concurrent conditions included non alcohol user, and non smoker. The patient had no known drug allergies and no any drug abuse / illicit drug use. The patient was previously treated with Clopidogrel bisulfate for drug used for unknown indication. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805031, and expiry: UNKNOWN) dose was not reported, 1 total administered on 18-MAR-2021 to left arm for prophylactic vaccination. Concomitant medications included amlodipine, metformin, metoprolol, and vitamin b complex all for drug used for unknown indication. On 28-MAR-2021, the subject experienced left leg calf pain. Patient reported that he experienced left leg pain below calf muscle and went to hospital and was further diagnosed with blood clot in left leg on 16-APR-2021. He was on Plavix and asked to stop Plavix on 16-APR-2021 by physician and placed on Eliquis 10 mg for the first 7 days twice a day and then 5 mg once a day for blood clot in left leg as treatment administered and with further concern to physician. He had appointment to hematologist for further follow up on 26-APR-2021. Laboratory data included: Diagnostic ultrasound (NR: not provided) Blot clot to left lower leg on 16-APR-2021. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from left leg calf pain, and blood clot in left leg. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This is a 78 year old male patient, who experienced left leg calf pain 10 days after receiving the Janssen COVID-19 vaccine on his left arm. 29 days after receiving the vaccine, patient sought consult for the left leg pain and was further diagnosed with blood clot on the left leg by diagnostic ultrasound. Patient's weight is 220 pounds and has a height of 67 inches. Patient is non smoker and does not take alcoholic beverages. Patient has no known history of drug allergies or drug abuse. Past medical history include having stent placed on him but he could not recall where the stent was placed. Patient was on Clopidogrel bisulfate but was asked to stop on the day he was diagnosed with the blood clot. Other concomitant medications include: amlopidine, metformin, and vitamin B complex. Indication for all medications being taken is unknown. Age and obesity (BMI = 34.5 per weight and height provided) are known risk factors for developing blood clot in the lower leg. Having a stent and concomitant medication suggest a cardiac problem. Based on the available information and considering the temporal relationship, the events of left leg calf pain and blood clot are assessed as indeterminate per WHO causality classification of adverse events following immunization.</p>
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COVID19 VACCINE	JANSSEN	1241202-1	50-59 years	Unknown	<p>BILATERAL PULMONARY EMBOLISM; UNSPECIFIED ISSUE WITH SPLEEN; DIZZINESS; HEADACHE; This spontaneous report received from a healthcare professional (nurse practitioner) via a company representative concerned a 54 year old female patient. The patient's height, weight were not reported and medical history was not known. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total administered (anatomical vaccination site unspecified) on 16-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date in MAR-2021, "about one week prior to admission", the subject experienced headaches and dizziness. On 03-APR-2021, the patient was admitted to hospital for bilateral pulmonary embolism and something with her spleen. The reporter believed that the patient had tests done on spleen (not further specified). Initially it was reported that the patient was out of hospital now and doing much better, but later it was clarified that patient has not yet been discharged from hospital. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the bilateral pulmonary embolism, unspecified issue with spleen, headache and dizziness was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: This 54-year-old female patient experienced headache and dizziness unspecified days after receiving covid-19 vaccine ad26.cov2.s for prophylactic vaccination. The patient was hospitalized 1 week later for bilateral pulmonary embolism (PE) and unspecified issue with spleen. Medical history and concomitant medications were reported. No other details of the events were reported. The patient had not yet been discharged from hospital. Based on a limited information, the events of bilateral PE, unspecified issue with spleen, headache and dizziness are assessed to have an indeterminate causal association to immunization, per the organization causality classification for adverse events following immunization. Company causality is considered not related to covid-19 vaccine ad26.cov2.s. Additional information has been requested for further assessment."</p>
COVID19 VACCINE	JANSSEN	1245569-1	50-59 years	Unknown	<p>THROMBOEMBOLIC COMPLICATION; This spontaneous report received from a patient concerned a 56 year old male. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included cardiovascular comorbidities. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, Expiry Date: UNKNOWN) with unknown dose, 1 total, on unspecified date for prophylactic vaccination. The batch number was not reported. The Company was unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient experienced thromboembolic complication, and was hospitalized (date unspecified). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of thromboembolic complication was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: This 56-year-old male patient, with unspecified cardiovascular comorbidities, was reported in the news to have a "thromboembolic complication" and was hospitalized after an unspecified duration of receiving Janssen COVID-19 vaccine for the prevention of symptomatic SARS-CoV-2 virus infection. No other details were reported. Based on the information that is available, the event is assessed as indeterminate with the causal association to immunization, per organization causality classification of adverse events following immunization based on a lack of a definitive plausible biological mechanism. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information will be requested once contact information is obtained"</p>

COVID19 VACCINE	JANSSEN	1248632-1	Unknown	Unknown	<p>VENOUS CLOT AND THROMBOSIS; This spontaneous report received from a physician via a company representative concerned a patient of unspecified age, ethnicity, and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient experienced venous clot and thrombosis, and was hospitalized (date unspecified). It was reported that the patient was currently hospitalized and the physician was asking for information in regards to anticoagulation therapy. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of venous clot and thrombosis was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition); Sender's Comments: V0: A patient of unspecified age, ethnicity, and sex experienced venous clot and thrombosis an unknown time after vaccine. This was reported by a physician to a company representative. No laboratory values are reported. No clinical history, medical history, medications, or details are reported. There is insufficient information to make a meaningful medical assessment. Additional information has been requested including attempted contact with the treating physician.</p>
COVID19 VACCINE	JANSSEN	1249220-1	Unknown	Unknown	<p>ELEVATED CLOT LEVELS; DIZINESS/LIGHTHEADED; NAUSEA; BRUISE ON LEG; SWELLING; WISDOM TOOTH PULLED; This spontaneous report was received from a consumer and concerned a female of unspecified age and sex, White, Hispanic or Latino. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number and expiration date: Unknown) dose was not reported, 1 total administered on 11-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. The patient's father reported that on 06-Apr-2021, in urgent care patient's wisdom tooth was pulled. On 08-APR-2021, the subject experienced dizziness/lightheaded, nausea, bruise on leg, swelling 4x4 inches on lower right calf. The next day, the patient's bruise/swelling move to inside of right knee, she had new bruise on leg and went to urgent care; the doctor told her she hit it. On 09-APR-2021, the bruise moved to inside of knee, and the patient was taken to emergency room (ER) where ""clot test"" showed elevated clot levels and rivaroxaban (Xarelto) was prescribed for treatment. On 10-APR-2021 (Saturday morning), ultrasound was done; result not reported. At the time of report there was decreased in swelling. The patient's father stated that, the event's might be related to wisdom tooth pulled. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from elevated clot levels, dizziness/lightheaded, nausea, bruise on leg, and swelling. This report was serious (Other Medically Important Condition); Sender's Comments: V0: This is a female patient, unspecified age, unspecified ethnicity, who experienced elevated clot levels 29 days after receiving the Janssen COVID-19 vaccine and 3 days after the patient's wisdom tooth was pulled out. The patient had her wisdom tooth pulled out 26th day post vaccination. 2 days later (28 days after the vaccination), the patient experienced dizziness and nausea and was noted to have bruise and swelling (around 4x4 inches) on the right lower leg. The next day, bruise/swelling was noted to reach the area of the right knee, probably the medial side, which prompted consult at the ER. The ""clot test"" done as was noted to be elevated (no actual results provided). An ultrasound was also done but the result was not reported. Long periods of immobility (sitting in the dental chair) and the temporal plausibility from the dental procedure to the event of elevated clot levels confounds the temporal plausibility of the elevation of clot level and the vaccine; hence this is assessed as indeterminate per WHO classification of adverse event following immunization. Additional information requested.""</p>

COVID19 VACCINE	JANSSEN	1249224-1	Unknown	Unknown	BLOOD CLOT IN CORONARY REGION; This spontaneous report received from a patient via a company representative concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unk) dose was not reported, administered on 10-APR-2021 for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On APR-2021, the patient experienced blood clot in coronary region. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot in coronary region was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This is a male, unspecified age, unspecified ethnicity, who experienced blood clot in coronary region after he received the COVID-19 vaccine ad26.cov2.s on an unspecified date. No other details given. The information provided precludes a meaningful medical assessment. Additional information requested.
COVID19 VACCINE	JANSSEN	1249239-1	Unknown	Unknown	BLOOD CLOTS; This spontaneous report received from a company representative via social media post and concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported, one total dose is administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow up will be requested. No concomitant medications were reported. On an unspecified date, the subject experienced blood clots. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clots was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This patient reported via social media to have blood clots and to have received the COVID-19 vaccine ad26.cov2.s. No other information provided. There is insufficient information to make a meaningful assessment. Additional information will be requested.

COVID19 VACCINE	JANSSEN	1249271-1	65+ years	Unknown	<p>FAST HEART RATE, BLOOD CLOT IN BOTH LUNGS, ACHY, LOW ENERGY, VERY WEAK, HEADACHE, FEVER, THIS spontaneous report received from a patient concerned a 72 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included fibromyalgia. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805022, and expiry: UNKNOWN) dose was not reported, administered on left arm on 13-MAR-2021 for prophylactic vaccination. Concomitant medications included pregabalin(Lyrica) for fibromyalgia and bad back. The patient reported pregabalin makes her gait off. On 13-MAR-2021, the patient felt okay. On 14-MAR-2021, the patient experienced achy, low energy, very weak, headache, fever of 100 degrees fahrenheit. Laboratory data included: Body temperature (NR: not provided) 100 F. On 13-APR-2021, she had wellness visit. The patient had a fast heart rate. Laboratory data included: Heart rate (NR: not provided) 144 (units unspecified). So immediately her electrocardiogram was taken and she was hospitalized for 2 days in emergency room by ambulance and started running tests. The patient had a computer tomography with dye contrast and it showed blood clots in both lungs. She had many tests, echocardiogram and X-rays. Treatment medications (dates unspecified) included: continuous oxygen via nasal prong (3.2 litre down to 2 litre), warfarin sodium(Coumadin), blood, whole, and rivaroxaban(Xarelto). The patient stated once she had rivaroxaban she felt ""free"". Currently also had 2 intravenous and taking blood regular. She was also on physical therapy. The therapist came in and made her walk across her room twice according to therapist she did not need oxygen. The patient currently had 2 IV's and taking blood regular. The patient will be discharged with or without the oxygen. The patient has machine on her chest with all kinds of wires. She don't know about her oxygen saturation. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from achy, low energy, very weak, headache, and fever on 15-MAR-2021, had not recovered from fast heart rate, and the outcome of blood clot in both lungs was not reported. This report was serious (Hospitalization Caused / Prolonged and Life Threatening).; Sender's Comments: V0: This is a 72 year old female, unspecified ethnicity, who experienced tachycardia and was noted to have blood clots in both lungs 32 days (around 1 month) after receiving the COVID-19 vaccine ad26.cov2.s on the left arm. Patient had Fibromyalgia and is maintained on Pregabalin (Lyrica). Patient's height and weight were not reported as well as history of smoking, allergies or drug abuse. One day after receiving the vaccine, the patient experienced fever, headache, weakness and pain, which resolved. During a wellness visit after a month from the vaccine, tachycardia was noted and an EKG was done. Patient was immediately brought to the ER, where the CT Scan (with contrast) showed blood clots in both lungs (detailed result not reported). Other tests done were also not reported. Patient was subsequently admitted in the hospital and was discharged after 2 days. The information provided is insufficient to show that the vaccine is causing the event; hence, this is assessed as indeterminate per WHO causality classification of adverse event following immunization. Additional information requested.""</p>
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COVID19 VACCINE	JANSSEN	1249273-1	Unknown	Unknown	<p>BILATERAL BLOOD CLOTS IN LEFT AND RIGHT LOWER LUNGS; This spontaneous report received from a patient via a company representative concerned a 46 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry: unknown) dose was not reported, 1 total administered on 05-APR-2021 for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 08-APR-2021, the patient experienced mild chest pain and dyspnea. On 14-APR-2021, the patient visited to emergency room and diagnosed with bilateral blood clots in left and right lower lungs. The patient had no prior medical history of blood clot and pulmonary issues. On 14-MAR-2021, treatment medications included: rivaroxaban. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of bilateral blood clots in left and right lower lungs was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This is a 46 male patient, unspecified ethnicity who was noted, at the emergency room (ER), to have bilateral blood clots in left and right lower lungs 9 days after receiving the covid-19 vaccine ad26.cov2.s. Weight and height were not reported. Medical history, smoking history and concomitant medications were not reported. Six (6) days prior to the visit to the emergency room, the patient experienced mild chest pains and dyspnea. Patient was sent home from the ER with Rivaroxaban. Based on the available information and considering the temporal causality, this is assessed as indeterminate per WHO causality classification of adverse reaction following immunization.</p>
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COVID19 VACCINE	JANSSEN	1249274-1	Unknown	Unknown	<p>BLOOD CLOT IN LEFT LUNG; SHORTNESS OF BREATH; DIARRHEA; LEG PAIN; INJECTION SITE PAIN; HEADACHE; SWEATING; DIZZINESS/FEELING FAINT; This spontaneous self-report was received from a patient and concerned a 29 year Black Mexican, White (Hispanic or Latino) old female. The patient's height and weight were not reported. The patient's concurrent conditions included hypertension, latex allergy, allergic to banana, and non smoker. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: 205A21A expiry: UNKNOWN) dose was not reported, 1 total dose on left arm administered on 08-APR-2021 (Thursday) for prophylactic vaccination. Concomitant medications included labetalol and nifedipine for hypertension. On 08-APR-2021, when patient received a vaccination it hurt at the time of injection. Later, she developed a headache. At night, she woke up with sweating. She went down to the kitchen and felt shortness of breath and felt faint. On 09-Apr-2021 (Friday), after she woke up, she developed diarrhea all day. On 10-APR-2021 (Saturday), her symptoms were continuing included diarrhea, sweating, dizziness, legs hurting, headache, and feeling shortness of breath. On 11-APR-2021 (Sunday), she felt better, however headache was ongoing. At night, she started feeling bad again. On 12-APR-2021, she woke up with diarrhea and sweating, no symptoms have resolved. On 13-APR-2021, her legs continued to be in pain. At night, she went to emergency room (ER) and have blood work done, showing it was positive for a blood clot. Her computerized axial tomography (CAT) was performed and blood clot in left lung was found. Her doctor said that all other blood work came back normal, and he did not see anything else wrong with her, and that the blood clot was related to the vaccine. He wanted to put her on a blood thinner and prescribed Eliquis (apixaban). Doctor mentioned that if she felt shortness of breath or started feeling dizzy, she must go to the hospital. It was reported that she was hospitalized for 1 day, and both admission and discharge dates were reported 13-APR-2021. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from blood clot in left lung, injection site pain, headache, sweating, shortness of breath, dizziness/feeling faint, leg pain, and diarrhea. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: This is a 29 year old male patient, who experienced leg pain and noted to have blood clot in the left lung 1 day and 5 days, respectively, after receiving the COVID-19 vaccine ad26.cov2.s on the left arm. Height and weight not reported. Patient has hypertension and is taking Labetalol and Nifedipine. Patient has history of allergy to latex and banana. Patient is not a smoker. Few hours after receiving the vaccine, patient developed headache, sweating, dizziness and shortness of breath. The following day, patient had diarrhea and experienced leg pain, laterality not reported. The symptoms were persistent and, 5 days after the vaccine, patient sought consult at the Emergency Room (ER) where the CAT scan showed blood clot in left lung. Patient was prescribed with Apaxiban. The information provided precludes a meaningful medical assessment. Additional information requested.</p>
COVID19 VACCINE	JANSSEN	1249278-1	Unknown	Unknown	<p>BLOOD CLOT IN LEFT LUNG; This spontaneous report received from a consumer concerned a female of unspecified age (in late 40's or early 50's) and ethnicity unspecified. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, Expiry: UNKNOWN) dose, 1 total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient was diagnosed with blood clot in her left lung after receiving the vaccine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This female patient of unspecified ethnicity, in her late 40's or early 50's, was reported to have blood clot in her lungs after an unspecified duration from receiving Janssen COVID-19 vaccine for the prevention of symptomatic SARS-CoV-2 virus infection. No other details was reported. Based on the information that is available, the event is assessed as indeterminate with the causal association to immunization, per WHO causality classification of adverse events following immunization based on a lack of a definitive plausible biological mechanism. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information will be requested once contact information is obtained</p>

COVID19 VACCINE	JANSEN	1249321-1	Unknown	Unknown	<p>SUPERFICIAL LEG THROMBOSIS; CHEST CONGESTION; TERRIBLE HEADACHE; LEGS WERE FROZEN; BRUISES ON HER LEGS; This spontaneous self-report was received from a patient and concerns a 68 year old female of unspecified race and ethnicity. Initial information received from the patient on 13-APR-2021 was processed with additional information received from the patient on 14-APR-2021 and telephone follow up with the patient on 20-APR-2021. The patient's weight and height were not reported. The patient had tuberculosis and had completed TB medication course. The patient does not have hypertension or diabetes. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration, date, vaccination site, and batch number were not reported) for prophylactic vaccination. The batch number will be requested in follow up. The patient was not taking any concomitant medications. On the third day after vaccination, the patient experienced terrible headache. Two days later, both her legs were frozen, and she had bruises on her legs. She went to a physician who advised her to go to the Emergency Room (ER), where they did an ultrasound on her legs. The physician told her that she had superficial leg thrombosis and asked her to take aspirin. No labs or any other diagnostic tests were performed. On the fifth day post-vaccination, the patient had chest congestion for 1 day. At the time of report, the patient was feeling better, and her bruises were disappearing. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from chest congestion and terrible headache, and was recovering from superficial leg thrombosis, legs were frozen, and bruises on her legs. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This 68-year-old female patient of unspecified ethnicity was found to have superficial blood clots in both legs 5 days after receiving COVID-19 VACCINE AD26.COV2.S intramuscularly for the prevention of symptomatic SARS-CoV-2 virus infection. The patient reported ""terrible"" headache 3 days after vaccination, ""chest congestion"" and that both her legs were ""frozen"" and with bruises 5 days after vaccination. Ultrasound on both legs showed superficial leg thrombosis during emergency room consultation and was advised to take aspirin as treatment. The event is recovering. Based on the information that is available, the event is assessed as plausible per the causality classification for adverse events. Considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information has been requested for further assessment.""</p>
COVID19 VACCINE	JANSEN	1249328-1	Unknown	Unknown	<p>BLOOD CLOT; This spontaneous report was received from a female patient of an unspecified age. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine Ad26.COV2.S (suspension for injection, route of administration, and batch number were not reported) dose, vaccination site, and start therapy date were not provided, for prophylactic vaccination; and was treated with XARELTO (rivaroxaban; film-coated tablet, oral, batch number was not reported) dose, frequency, and therapy dates were not provided, for an unknown indication. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient experienced a blood clot. The patient reported she got a blood clot after receiving her vaccine, and that she had just started taking rivaroxaban. Action taken with Covid-19 vaccine Ad26.COV2.S was not applicable, and action taken with rivaroxaban was not reported. The patient outcome for the event of blood clot was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: v0 This report involves a female patient of unspecified age who experienced a blood clot on an unspecified date after receiving the Janssen COVID-19 Vaccine Ad26.COV2. Concomitant medications included rivaroxaban (recently started). The patient's past medical history and details of the event were not reported. The recent starting of rivaroxaban infers a recent clot or a condition that would predispose the patient to develop a clot, however this case has insufficient information to make a meaningful medical assessment.</p>

COVID19 VACCINE	JANSSEN	1249336-1	Unknown	Unknown	<p>THROMBOSIS IN MY RECTAL AREA; ARM VERY SENSITIVE TO THE TOUCH; SEVERE HEADACHE; CHILLS; SORE ARM; This spontaneous self-report was received from a patient of unspecified sex, age, race and ethnicity. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration, dose, vaccination site, and batch number were not reported, ) administered on 16-MAR-2021 at 13:00 for prophylactic vaccination. The batch number will be requested in follow up. No concomitant medications were reported. On 16-Apr-2021 in the evening post vaccination, the patient had severe headache and chills. The headache continued the whole next day, but was not as bad as the first evening. Her arm was very sore, and it hurt to move it the first day, and then very sensitive to the touch the next day, and continued for a whole week. On 29-Apr-2021 (13 days post vaccination), "" thrombosis (according to my doctor) appeared in my rectal area that still hasn't gone away"". The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from arm very sensitive to the touch, severe headache, and sore arm, had not recovered from thrombosis in my rectal area, and the outcome of chills was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This patient of unspecified age, gender, and ethnicity reported to have ""thrombosis (according to my doctor) appeared in my rectal area that still hasn't gone away"" 13 days after receiving Janssen COVID-19 vaccine for the prevention of symptomatic SARS-CoV-2 virus infection. The patient also reported severe headache and chills on the day of vaccination that persisted until the following day, as well as arm soreness that persisted for a whole week. No other details was reported. Based on the information that is available, the event is assessed as indeterminate with the causal association to immunization, per WHO causality classification of adverse events following immunization based on a lack of a definitive plausible biological mechanism. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information is requested""</p>
COVID19 VACCINE	JANSSEN	1249343-1	Unknown	Unknown	<p>CLOT OF ABOUT 3-4 INCHES; LOWER LEG PAIN; This spontaneous report received from a patient via a company representative concerned a 35 year old male. The patient's weight, height, and medical history were not reported. The patient had no history of blood clots and is active. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry: unknown) dose was not reported, 1 total administered on 23-MAR-2021 for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date in 2021, the patient experienced lower leg pain. About a week after that, on an unspecified date in 2021, the patient experienced clot of about 3-4 inches confirmed by ultrasound. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the lower leg pain and clot of about 3-4 inches was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This 35-year-old male patient of unknown ethnicity was reported in social media to have ""clot of about 3-4 inches confirmed by ultrasound"" after an unspecified duration from receiving Janssen COVID-19 vaccine for the prevention of symptomatic SARS-CoV-2 virus infection. This was preceded by symptom of lower leg pain 1 week prior. No other details was reported. The information available precludes a complete and meaningful assessment. The case will be re-assessed once additional information is received.""</p>

COVID19 VACCINE	JANSSEN	1249385-1	40-49 years	Unknown	<p>HAD BODY ACHE; HAD HEADACHE; PULMONARY EMBOLISM IN BOTH LUNGS; SHORTNESS OF BREATH; CHARLIE HORSE IN LEGS IN MIDDLE OF NIGHT; LOWER EXTREMITIES HURTING AND SWELLING; HAD FLU-LIKE SYMPTOMS; TIRED/LETHARGIC; This spontaneous report received from a patient concerned a 49 year old female. The patient's height, and weight were not reported. The patient was a non alcohol user and non smoker, and he took vitamins. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029, expiry: unknown) dose was not reported, administered on 19-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On an unspecified date progressively 4 days after receiving vaccine the patient had headache and had body ache. On 21-MAR-2021, the patient had flu-like symptoms and felt tired/lethargic. On 24-MAR-2021, the patient had lower extremities hurting and swelling. On 26-MAR-2021, the patient felt charlie horse in legs in middle of night. On 01-APR-2021, the patient had shortness of breath and he could not catch her breath. At that point patient went to emergency room. In emergency room the patient underwent CT scan and revealed with small clots in lower lobe of both lungs. The patient was treated with 40 mg Eliquis for treatment. The emergency room doctor advised consumer to saw pulmonary specialist and follow up with him primarily. On 15-APR-2021, the patient had pulmonary embolism in both lungs. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from had flu-like symptoms, and had not recovered from pulmonary embolism in both lungs, lower extremities hurting and swelling, shortness of breath, tired/lethargic, charlie horse in legs in middle of night, headache, and body ache. This report was serious (Other Medically Important Condition); Sender's Comments: V0: This is a 49 year old female patient, African American, who experienced pain on lower extremities and was noted to have small clots in the lower lobes 5 days and 13 days, respectively, after receiving the the COVID-19 vaccine ad26.cov2.s. Patient's height and weight were not reported. Patient is a non smoker and non alcoholic beverage drinker. Past medical history not reported and patient denied taking medications, except vitamins. Four (4) days after receiving the vaccine, patient experienced flu like symptoms. lethargy, headache and body ache which were noted to resolve. Five (5) days after receiving the vaccine, patient developed pain on the lower extremities and patient noted to fell charley horse (muscle spasm and pain). Thirteen (13) days after receiving the vaccine, patient experienced shortness of breath, which prompted consult at the emergency room. CT Scan done revealed small clots in the lower lobe of both lungs. Patient was noted to have pulmonary embolism. The temporal relationship may be consistent but there is insufficient evidence for the vaccine to cause the events; hence this is assessed as indeterminate per causality classification of adverse events following immunization. Additional information requested.</p>
COVID19 VACCINE	JANSSEN	1249401-1	Unknown	Unknown	<p>BLOOD IN URINE WITH CLOTS; BODY ACHES/WHOLE BODY HURT; MUSCLE ACHES; This spontaneous report received from a patient concerned a 73 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included high blood pressure. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808980, expiry: UNKNOWN) dose was not reported, frequency 1 total, administered on 07-APR-2021 to left arm for prophylactic vaccination. Concomitant medications included medication for high blood pressure. On 08-APR-2021, the patient's ""whole body hurt"" with muscle aches and body aches. On 16-APR-2021, the patient experienced ""blood in urine with clots"", sometimes the clots were dry and other times they were wet. Patient experienced blood in urine each time he urinated having started on 16-APR-2021 and he had never experienced this prior to receiving the vaccine. Patient stated that he did not experience any other side effects such as fever, abdominal pain or leg pain. Patient had not yet sought medical attention and had not taken any medications to treat his adverse effects. Patient stated that he had planned to reach out to a healthcare professional on 19-APR-2021 (tomorrow). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the muscle aches, body aches/whole body hurt and blood in urine with clots was not reported. This report was serious (other medically important condition); Sender's Comments: V0:20210436909-Covid-19 vaccine .Ad26.Cov2.S-Blood in urine with clots. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).""</p>

COVID19 VACCINE	JANSSEN	1249414-1	60-64 years	Unknown	<p>CLOTS ON RIGHT LEG; HEADACHE; PRESSURE ON BOTH LEGS; PRESSURE ON HANDS; This spontaneous report received from a patient via a company representative concerned a 64 year old Hispanic or Latino female. The patient's height, and weight were not reported. The patient's concurrent conditions included high blood pressure and diabetes. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029 expiry: UNKNOWN) dose was not reported, 1 total administered on 17-MAR-2021 at left arm for prophylactic vaccination. No concomitant medications were reported. On 17-MAR-2021, the patient had experienced headache after vaccination. On 27-MAR-2021, the patient began to experience intermittent pain on right leg. On 30-MAR-2021, she experienced headache again and was still having leg pain; she visited the Emergency Room (ER) and was admitted on 30-MAR-2021. On 02-APR-2021, the patient experienced clots on right leg. On APR-2021, a catheter was placed in catheterization procedure and her right leg vein was unclogged of a clot. A second clot did not require removal because the vein had already unclogged itself after medication. The patient was administered unspecified anticoagulants. She was discharged on 5-APR-2021 and was prescribed ticagrelor which was then changed to clopidogrel. On 18-APR-2021, the patient experienced a headache again and feeling of pressure on legs and hands. Patient was advised to visit ER. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from clots on right leg and intermittent pain on right leg on 02-APR-2021, recovered with sequelae from headache on 19-MAR-2021, and had not recovered from pressure on both legs and pressure on hands. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: This 64 year-old Hispanic or Latino female with history of high blood pressure and diabetes was hospitalized for clots in her right leg 13 days after receiving the Janssen Covid-19 vaccine. Concomitant medications were not reported. On the day of her vaccination, she experienced a headache. Ten days later, she began to experience intermittent leg pain. Three days later (ie, 13 days post vaccination), she went to the emergency room (ER) and was admitted to the hospital. During the hospitalization, a clot was removed via catheterization and she was administered unspecified anticoagulants. A second clot resolved on its own without surgical intervention. After 6 days in the hospital, she was discharged with ticagrelor which was later changed to clopidogrel. She recovered from the clots. Thirteen days after discharge, she began to experience headache and ""pressure"" in both legs and hands. She was advised to go to the ER; no further information was provided. Based on the limited information, the relationship of the serious events with Janssen Covid-19 vaccine is considered indeterminant. Additional information is being sought.""</p>
COVID19 VACCINE	JANSSEN	1256798-1	65+ years	Unknown	<p>Patient's daughter came to the pharmacy on 04/24/2021 and stated that her mother, the patient, got the Janssen vaccine here and within a week, she had a blood clot and has been in the hospital ever since. This is all the information we received.</p>

COVID19 VACCINE	JANSSSEN	1261176-1	50-59 years	Unknown	<p>BLOOD CLOT FOUND IN RADIAL ARTERY OF RIGHT ARM; SWELLING OF LYMPH NODES ON BOTH SIDES OF NECK; ARM SORENESS PROGRESSED TO ACHING OF RIGHT ARM; NUMB RIGHT ARM; FATIGUE; This spontaneous report was received from a patient and concerned a 51 years old female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: 1805025, expiry: unknown) dose was not reported, 1 total, administered on 16-MAR-2021 at her right arm for prophylactic vaccination. No concomitant medications were reported. On 16-MAR-2021, after receiving vaccine, the patient felt fatigue and right arm soreness where she got the vaccine. The arm soreness progressed to aching and numbness. On 01-APR-2021, the patient noticed swelling of lymph nodes on both sides of her neck. On the same day she was sent to emergency room (ER) and was told that a blood clot was found in the radial artery of her right arm; diagnostic data not reported. She was given Plavix (clopidogrel) and sent home. On 06-APR-2021, the patient returned to ER because she was not feeling any improvement on her right arm, and it was still hurting. She was told that a surgery was planned to remove the clot but it was later cancelled. She was sent home on the same day with XARELTO (rivaroxaban). At the time of report, the patient had a pending appointment with a surgeon regarding the clot; no date was provided. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from fatigue on 19-MAR-2021, was recovering from arm soreness progressed to aching of right arm, and numb right arm, and had not recovered from blood clot found in radial artery of right arm, and swelling of lymph nodes on both sides of neck. This report was serious (Other Medically Important Condition).; Sender's Comments: V0 This report concerns a 51 years old female patient who had a blood clot in the radial artery of her right arm, 15 days after receiving Jansen COVID-19 vaccine. On the same day of vaccination, patient experienced fatigue and right arm sore where she got the vaccine. The arm soreness progressed to aching and numbness. 15 days after vaccination, the patient noticed swelling of lymph nodes on both sides of her neck and was sent to ER. She was told that a blood clot was found in the radial artery of her right arm (diagnostic data not reported) and was treated with Plavix and later with Xarelto. Based on the reported information, the causality of event blood clot in the radial artery of her right arm is considered plausible to the vaccination. Additional information has been requested.</p>
COVID19 VACCINE	JANSSSEN	1261192-1	30-39 years	Unknown	<p>BLOOD CLOT FROM NOSE; TEMPORARILY UNABLE TO WALK, RICKETY KNEES; BURNING LEG PAIN; JOINT PAIN/ SHOULDER PAIN; SHOULDER FEEL TIGHT; This spontaneous report received from a patient concerned a 30 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included cigarette smoker (occasional pot; rarely). The patient's grandfather died from blot clot under knee (thrombosis). The patient had no history of bloody nose. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808609, expiry: UNKNOWN) dose was not reported, administered on left arm on 28-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 30-MAR-2021 (two days after vaccination) the patient experienced really bad burning leg pain for few days and his joints in shoulder and knees were affected two days after vaccination and he could not walk (temporarily unable to walk). The patient also experienced rickety knees. On the same day, the patient blew out a huge blood dot from his nose. On 2021, the patient's shoulder felt tight. At the time of this report, the patient's knees and shoulders were still feeling tight like there was hardly any cartilage. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from blood clot from nose, and temporarily unable to walk, rickety knees, was recovering from joint pain/ shoulder pain, and the outcome of burning leg pain and shoulder feel tight was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0-Covid-19 vaccine ad26.cov2.s-blood clot from nose. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY</p>

COVID19 VACCINE	JANSSEN	1261217-1	60-64 years	Unknown	<p>PULMONARY EMBOLISM; CHEST PAIN; This spontaneous report received from a patient via a company representative via the local news, concerned a 60 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) at an unspecified dose on 06-MAR-2021 for prophylactic vaccination. The anatomical vaccination site was not reported. The batch number was not reported. The company is unable to perform follow-up to request batch/lot number. No concomitant medications were reported. On 01-APR-2021, 26 days after vaccination, the patient went to hospital due to chest pain. On 08-APR-2021, 33 days after vaccination, the patient was diagnosed with pulmonary embolism, and was hospitalized. The patient reported he suffered a blood clot after receiving the vaccine and was diagnosed with a pulmonary emboli. On 11-APR-2021, the patient was discharged. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of pulmonary embolism and chest pain was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: VO: A 60-year-old man experienced chest pain 26 days after vaccine and was hospitalized with pulmonary emboli 33 days after vaccine. Medical history and concomitant medications were not reported. The latency of greater than 3 weeks makes this unlikely related to vaccine. There is insufficient information to make a meaningful medical assessment. Additional information has been requested, including contacting the news station that reported the event.</p>
COVID19 VACCINE	JANSSEN	1261249-1	50-59 years	Unknown	<p>BLOOD CLOT; LEG CRAMPS; ACHE; HEADACHE; FEVER; This spontaneous report received from a patient concerned a 50 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included overweight, high blood pressure, and high cholesterol. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 207A21A expiry: unknown) dose was not reported, 1 total administered on 06-APR-2021 to left arm for prophylactic vaccination. No concomitant medications were reported. On 07-APR-2021, the patient experienced a mild fever. On 08-APR-2021, the patient was achy and had a mild headache. The headache continued for several day and became pretty bad for about two days. On an unspecified date in Apr-2021 the patient was treated with Tylenol for headache. On 12-APR-2021, the patient experienced leg cramps in her right leg. On 15-APR-2021, the patient had an ultrasound and a blood clot was found in her right leg. The patient started on Apixaban (Eliquis). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from headache on an unknown date in APR-2021, and the outcome of blood clot, ache, leg cramps and fever was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: VO: This 50-year-old female was found to have blood clot in her right leg 9 days after receiving Janssen COVID-19 vaccine for the prevention of symptomatic SARS-CoV-2 virus infection. There was reported mild fever, headache, and ""aches"" 1 to 2 days after vaccination that was treated with Tylenol. The symptom reported was leg cramps on right leg 5 days after vaccination, and ultrasound showed blood clot in her right leg 3 days after the symptom of cramps was noted. No other laboratory/diagnostic test reported. The patient was treated with apixaban. The outcome of blood clot in leg was not reported. Based on the information that is available, the event is assessed as plausible with the causal association to immunization, per causality classification of adverse events following immunization based on a lack of a definitive plausible biological mechanism. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information is requested""</p>

COVID19 VACCINE	JANSSEN	1261282-1	Unknown	Unknown	LARGE BLOOD CLOT; SWOLLEN BALL ON SIDE OF KNEE; This spontaneous report received from a female patient of unspecified age reporting on self. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, Expiry: Unknown) dose was not reported, 1 total administered on 05-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient experienced large blood clot and swollen ball on side of knee. The swollen ball on side of knee was going on for a couple days now. The action taken with covid-19 vaccine ad26.cov2.s was not reported. The patient had not recovered from large blood clot, and swollen ball on side of knee. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This is a report of a female patient, unspecified age, unknown ethnicity, who experienced a large blood clot and swelling on the side of the knee (laterality not reported) on an unspecified number of days after receiving the cobid-19 vaccine ad26.cov.2. The information provided precludes a meaningful medical assessment. Additional information requested.
COVID19 VACCINE	JANSSEN	1261284-1	Unknown	Unknown	BLOOD CLOT IN FOOT; This spontaneous report was received from a patient via a company representative and concerned a male patient of unspecified age. The patient's weight, height, and medical history were not reported. The patient received COVID-19 vaccine Ad26.COVS.2.S (suspension for injection, route of admin not reported) 1 total dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, two days after vaccination, the patient experienced a blood clot in his foot. The action taken with COVID-19 vaccine Ad26.COVS.2.S was not applicable. The outcome of blood clot in foot was not reported. This report was serious (other medically important condition).; Sender's Comments: V0: This male of unspecified age and ethnicity reported to have experience blood clot in foot 2 days after receiving Janssen COVID-19 vaccine for the prevention of symptomatic SARS-CoV-2 virus infection. No other information was reported. Based on the information that is available, the event is assessed as plausible with the causal association to immunization, per WHO causality classification of adverse events following immunization based on a lack of a definitive plausible biological mechanism. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information is requested
COVID19 VACCINE	JANSSEN	1261302-1	65+ years	Unknown	BILATERAL PULMONARY EMBOLISMS; This spontaneous report received from a pharmacist concerned an 84 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805018, and expiry: 25/MAY/2021) dose was not reported, 1 total dose administered on 10-MAR-2021 in left arm for prophylactic vaccination. No concomitant medications were reported. 10-MAR-2021 After administration of vaccine on 15-APR-2021, patient had bilateral pulmonary embolisms and was hospitalized in local hospital then triaged to heart institute, Reporter also report patient will get discharged soon. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of bilateral pulmonary embolisms was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: This 84 year-old male patient was hospitalized for bilateral pulmonary embolisms 36 days after receiving the Janssen Covid-19 vaccine. Medical history, concomitant medications, social history, family history, diagnostic test results, corrective treatment, and outcome were not reported. Based on the limited information, the event is considered unclassifiable. Additional information is being sought.

COVID19 VACCINE	JANSSEN	1261322-1	40-49 years	Unknown	<p>CLOT BLOOD; ACUTE ISCHEMIC STROKE IN LEFT FRONTAL LOBE; PARTIAL LOSS OF USE IN RIGHT LEG; MUSCLE WEAKNESS; This spontaneous report received from a patient concerned a 46 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included amoxicillin and flexeril allergy, and migraine. The patient experienced drug allergy when treated with cyclobenzaprine hydrochloride. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 042A21A, and batch number: 042A21A expiry: UNKNOWN) dose was not reported, administered on 08-APR-2021 11:30 on left arm for prophylactic vaccination. Concomitant medications included ascorbic acid, ascorbic acid/ergocalciferol/folic acid/nicotinamide/panthenol/retinol/riboflavin/thiamine hydrochloride, ergocalciferol, iron, and withania somnifera. Approximately three days after the vaccine, on 11-APR-2021 08:20, the patient experienced clot blood. Which caused an acute ischemic stroke in left frontal lobe resulting in partial loss of use in right leg and muscle weakness. The patient had a blood test, CT scan, Carotid artery ultrasound, diagnostic ultrasound, electrocardiogram (EKG) and an MRI, results are unknown. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from clot blood, acute ischemic stroke in left frontal lobe, muscle weakness, and partial loss of use in right leg. This report was serious (Other Medically Important Condition); Sender's Comments: V0: This is a report of a 46 year old, female patient who experienced a blood clot that caused an acute ischemic stroke in the left frontal lobe 3 days after receiving the covid-19 vaccine ad26.cov.2. Patient's height and weight were not reported. Patient has migraine and allergies to amoxicillin, flexeril and cyclobenzapine hydrochloride. Concomitant medications included ascorbic acid, ascorbic acid/ ergocalciferol/folic acid/ nicotinamide/ panthenol/retinol/ riboflavin/ thiamine hydrochloride, ergocalciferol, iron, and withania somnifera. Smoking history, drug abuse and alcohol intake were not reported. Three (3) days after receiving the vaccine, patient was noted to have a blood clot (unspecified area) that caused an acute ischemic stroke in the left frontal lobe, resulting in muscle weakness and partial loss of use of the right leg. Patient had blood tests done as well as CT Scan, carotid artery ultrasound, electrocardiogram and MRI but the results were not reported. The information provided precludes a meaningful medical assessment. Additional information requested.</p>
COVID19 VACCINE	JANSSEN	1261329-1	30-39 years	Unknown	<p>THROMBOSIS; Dizziness; Pass Out; Weakness in the all side of the body; This spontaneous report received from a patient. The patient's height, and weight were not reported. The patient's concurrent conditions included sea food allergy, and other pre-existing medical conditions included the patient did not had any other illness at the time of vaccination and to one month prior and chronic or long standing health condition. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose was not reported, administered on 02-APR-2021 11:25 for prophylactic vaccination. The batch number was not reported. As per procedure, no follow-up will be requested for this case. Concomitant medications included metformin for drug used for unknown indication. On an unspecified date, the subject experienced thrombosis, dizziness, pass out, and weakness in the all side of the body, and was hospitalized (date unspecified). Laboratory data (dates unspecified) included: X-ray (NR: not provided) heart, head and lungs. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from thrombosis, dizziness, pass out, and weakness in the all side of the body. This report was serious (Hospitalization Caused / Prolonged, and Life Threatening); Sender's Comments: V0: This is a report of a patient, who was noted to have thrombosis on unspecified time after receiving the covid-19 vaccine ad26.cov.2. Patient's height and weight were not reported. Patient medical history was not reported. Concomitant medications included metformin for unknown indication. Patient is allergic to seafoods. On an unspecified date, the subject experienced dizziness and passed out. She also had weakness on the left side of the body. Patient was noted to have thrombosis. Patient was hospitalized, where laboratory and diagnostic tests were done. Results were not reported. The information provided precludes a meaningful medical assessment. Additional information requested.</p>

COVID19 VACCINE	JANSEN	1261352-1	Unknown	Unknown	<p>BLOOD CLOT IN RIGHT LUNG; This spontaneous report received from a patient via a company representative via email concerned a patient of unspecified age and sex. Patient's race and ethnicity were not reported. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin unknown) dose, anatomical vaccination site, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient experienced blood clot in right lung. The patient emailed in regards to a possible adverse event reaction to the Janssen Covid vaccine that he received on an unspecified date. The patient was in a hospital at the time of report with a blood clot in right lung. One of the doctor insinuated that it may have been caused by the vaccine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the event blood clot in right lung was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: This case concerns a patient of unspecified age and gender who experienced a blood clot in the right lung an unspecified period of time after receiving the Janssen Covid-19 vaccine. Medical history, concomitant medications, diagnostic tests, corrective treatments, and outcome were not provided. Based on the limited available information, the relationship to vaccination is considered unclassifiable. Additional information is being requested.</p>
COVID19 VACCINE	JANSEN	1261383-1	Unknown	Unknown	<p>BLOOD CLOTS IN THE LEG; BLOOD CLOT IN THE CHEST; This spontaneous report received from a consumer (calling on behalf of her husband) concerned a 60 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included diabetes mellitus, asthma, high blood pressure, and penicillin allergy. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin: unknown, batch number: Unknown) on 12-APR-2021, into right arm, for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 18-APR-2021, the patient began experiencing pain and swelling in the left leg. His leg was very hot and red ""like a fever"" and the pain was radiating up to the chest and heart and also spread to the right side of the chest. The patient was experiencing a lot of pain and couldn't breath. On 19-APR-2021 the patient's wife called the doctor and he was admitted to hospital. An ultrasound was performed which confirmed blood clots in the leg and chest. At the time of this report patient was still in the hospital. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clots in the leg, and blood clot in the chest. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: This 60 year-old male with medical history significant for diabetes, high blood pressure, and asthma was hospitalized for blood clots in the leg and chest 7 days after receiving the Janssen Covid-19 vaccine. Concomitant medications were not reported. Six days post-vaccination, the patient began experiencing left leg pain and swelling. His leg was red and hot and the pain would radiate from his leg to his chest. He was also experiencing difficulty breathing. The following day (7 days post-vaccination), he was admitted to the hospital. An ultrasound confirmed blood clots in the leg and chest. Other diagnostic test results and corrective treatment were not reported. As of the time of this report, the patient was still in the hospital. Based on the limited information, the relationship with Janssen Covid-19 vaccine is considered indeterminant. More information (e.g. platelet count, D-dimer, fibrinogen, anti-platelet factor 4 antibodies, medical records) is being sought.""</p>

COVID19 VACCINE	JANSEN	1261384-1	Unknown	Unknown	<p>SWOLLEN NECK; SWOLLEN RIGHT ARM; 6 BLOOD CLOTS; SICK; This spontaneous report received from a patient concerned a male of unspecified age. The patient's height, and weight were not reported. The patient's past medical history included surgery. There was no history or family history of blood clots. Prior to vaccination, the patient had several physicals performed due to other health concerns and CAT-scans and MRIs were performed that showed his body was totally without any blood clots. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic indication. Batch number was not reported and has been requested. No concomitant medications were reported. After getting the vaccine patient was sick for 3 days. On an unspecified date, the patient woke with a with swollen neck, swollen right arm that was twice its normal size. The patient went to the hospital and they were concerned it was a blood clot further so he was then sent to hospital where they performed an ultrasound which revealed 6 blood clots. The patient was hospitalized and underwent surgery on his arm to ""open up the vein that was causing the swelling"". The patient reported he was scheduled for several more surgeries of this kind. Corrective treatment included intravenous blood thinners. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from swollen neck, swollen right arm, 6 blood clots, and sick. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: VO: This male patient of unspecified age noted swelling of righ arm and neck that the ultrasound showed 6 blood clots after an unspecified duration from receiving Janssen COVID-19 vaccine for the prevention of symptomatic SARS-CoV-2 virus infection. The patient was hospitalized and underwent corrective surgery and was started on unspecified blood thinners. No other details was reported. The information available precludes a complete and meaningful assessment. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information was requested.""</p>
COVID19 VACCINE	JANSEN	1264464-1	40-49 years	Unknown	<p>BLOOD CLOTS IN URINE; URINATING BLOOD; FELT ACHY; This spontaneous report received from a patient concerned a 43 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805020, and expiry: 25-MAY-2021) dose was not reported, administered, 1 total, to left arm on 19-MAR-2021 around 06:00 PM for prophylactic vaccination. No concomitant medications were reported. On 20-MAR-2021, 12 hours after vaccination patient felt achy which had resolved in 24 hours. On 20-APR-2021, patient experienced blood clots in urine and had urinating blood lasted till evening of same day. The patient visited emergency room for same symptoms and admitted on 20-APR-2021, discharged around noon on same day. The patient was given with IV fluids and no other medications were administered. The patient had undergone blood test, urine analysis, computerized tomography (CT) scan and results were nothing urgent to consult. The patient had planned to do follow-up with urologist on 28-APR-2021. Laboratory data included: Blood test (NR: not provided) negative, computerized tomography (CT) scan (NR: not provided) negative, and Urinalysis (NR: not provided) negative. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from blood clots in urine, and urinating blood on 20-APR-2021, and felt achy on 21-MAR-2021. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: VO: - Covid-19 vaccine .Ad26.Cov2.S- Blood clots in urine . This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

COVID19 VACCINE	JANSSEN	1264472-1	50-59 years	Unknown	<p>POSSIBLE PULMONARY EMBOLISM; ELEVATED D-DIMER; This spontaneous report received from a patient concerned a 55 year old female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: ER8729, and expiry: UNKNOWN) dose was not reported, 1 total administered on 07-APR-2021 at around 10:00 on left arm for prophylactic vaccination. No concomitant medications were reported. On 16-APR-2021, the patient experienced shortness of breath that worsened with exertion, and at the time of reporting at rest. Patient called her physician (MD) (internist) and went to the office on 23-APR-2021 for some testing. She had an elevated d-dimer level. Laboratory data included: Fibrin D dimer high (NR: not provided) Elevated. The physician treated her for possible pulmonary embolism. On same day she experienced pressure in her chest. At the time of reporting patient had shortness of breath and occasionally some pressure in her chest. Patient did not take any medications for her symptoms. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from elevated d-dimer, and possible pulmonary embolism. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: This spontaneous case describes a 55-year-old female who experienced shortness of breath which worsened with exertion 9 days after receiving the Janssen COVID-19 vaccine. She then experienced chest pressure 16 days after vaccine administration, and saw her physician that day. D-dimer level was elevated, and the physician treated her for a possible pulmonary embolism. Medical history and concomitant medications were not provided. The patient had not recovered from the events. There are insufficient details in the case to make a meaningful medical assessment. The case will be assessed further when additional information is received.</p>
COVID19 VACCINE	JANSSEN	1265873-1	Unknown	Unknown	<p>STROKE; BLOOD CLOT IN LEG; This spontaneous report received from a consumer concerned a 51 year old male. The patient's height, and weight were not reported. The patient's pre-existing medical conditions included the patient was healthy with no health issues. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose, start therapy date were not reported, 1 total administered for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. It was reported that on an unspecified date in 2021, the patient started with symptoms after 13 days of vaccination. The patient woke with leg pain That morning, he got in the vehicle to go to work and pulled over due to heaviness in his left arm and slurred speech. An ambulance was called and they took him to the emergency room. From there he was life flighted to another hospital and was continued with laboratory tests. Laboratory data included: doppler ultrasound (NR: not provided) not reported, MRI (magnetic resonance imaging) (NR: not provided) not reported, scan (NR: not provided) not reported and other tests. It was due to the blood clot in his leg that caused him to suffer a stroke. He spent days in the hospital and had to wear a heart monitor for two weeks. He was on blood thinners until further notice to prevent this from happening again. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the blood clot in leg and stroke was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: This case concerns a 51 year-old male with no prior medical issues who was hospitalized for a stroke and blood clot in his leg 13 days after receiving the Janssen Covid-19 vaccine. Concomitant medications, family history, and social history were not reported. Thirteen days post-vaccination, the patient awoke with leg pain. While driving to work, he experienced heaviness in his left arm and slurred speech and pulled his car over. An ambulance took him to a local hospital and from there, he was air-lifted to another hospital where doppler ultrasound, MRI, and other unspecified tests were performed. He spent an unspecified number of days in the hospital and wore a heart monitor for 2 weeks. He was treated with blood thinners. Per the reporter (patient's daughter), the blood clot caused the stroke. Outcome was not reported. Based on the available information, the relationship with Janssen Covid-19 vaccine is considered indeterminant. More information (e.g. platelet count, D-dimer, fibrinogen, anti-platelet factor 4 antibodies, medical records) is being sought.</p>

COVID19 VACCINE	JANSSEN	1268728-1	40-49 years	Unknown	<p>HEADACHE/PAIN IN HEAD; HEAD FELT FLUIDY,FLOATING,FOGGY,/FREAKING OUT; FLUCTUATING LUCIDITY/FELT LUCID; PAIN IN NECK; WOKE UP AND STUMBLED; RED BLOOD (AND CLOT) WHEN BLEW NOSE; RED BLOOD (AND CLOT) WHEN BLEW NOSE; DREAMING DIZZY/DIZZY; FEELS JITTERY/NOT FEELING WELL; This spontaneous report received from a 49 year old female patient reporting on self. The patient's height, and weight were not reported. The patient's concurrent conditions included seasonal allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808982,expiry: UNKNOWN) dose was not reported,1 total administered on 12-APR-2021 09:00 in right arm for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, in the evening she had headache. On 12-APR-2021 the patient was dizzy and not feeling well at night she woke up in sleep feeling dizzy as she was dreaming dizzy, got up from bed and stumbled. She told her husband not feeling well but he tried to brush it aside. up from bed and stumbled. She took Advil. The doctor on-call told her to calm down and to take 2 Advil and went to sleep and if it did not went away to ER. The consumer did so. On 13-APR-2021, (Tuesday morning) the consumer blew her nose and noticed red blood and clots (coming from further up higher than sinuses). She was concerned and talked to people (friends). On 14-APR-2021, around 3:00 Wednesday morning she was freaking out she called her doctor and was not available she was referred to another physician. The patient was lucid, head felt fluidy, floating and dizzy. She had pain in the head and the neck. On 15-APR-2021, Thursday morning the physician called her back and said to stop taking Advil and went to ER. Her head was heavy and fog, everything was slow and lucid. In the hospital as soon as they gave her saline IV fluid, the fog was half lifted. Laboratory data (dates unspecified) included they also did MRI and blood work which were normal. They discharged her the same day and suggested she could take Tylenol which she did Thursday night. On 16-APR-2021, Friday she felt jittery but good and will buy some Gatorade for hydration and patient also stated that both dizzy and heavy head was reduced to faint (coming down from 10 to 3.5 on a scale). The consumer suggested that the dose of the vaccine may be too much for certain individuals and suggested to reduce the dose to like half the dose or to give it in 2 shots. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from red blood (and clot) when blew nose, and stumbling on 15-APR-2021, was recovering from dizziness, fluctuating lucidity, head felt fluidy, floating, foggy,/freaking out, pain in neck, and feels jittery/not feeling well, and the outcome of headache/pain in head was not reported. This report was serious (Other Medically Important Condition); Sender's Comments: 20210436432- covid-19 vaccine ad26.cov2.s-head felt fluidy, floating, foggy,/freaking out, red blood (and clot) when blew nose. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>
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COVID19 VACCINE	JANSSEN	1269146-1	50-59 years	Unknown	<p>DVT POST COVID INJECTION; This spontaneous report received from a patient concerned a 52 year (also reported as 53 year) old male. The patient's height, and weight were not reported. The patient's past medical history included provoked DVT (deep vein thrombosis) 10 years ago, and concurrent conditions included hypertension. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: Unknown) dose was not reported, administered on 12-APR-2021 into left deltoid for prophylactic vaccination. The product was properly stored from receipt to administration. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. Patient received J&amp;J vaccine at place of employment. After 24 hours on an unspecified date in APR-2021, the patient developed lower leg DVT (deep vein thrombosis) post COVID injection. It was confirmed by positive d-dimer (coded as Fibrin D dimer) and US (ultrasound scan). Exact results and date of the tests were not provided. The patient was started on rivaroxaban. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of DVT post COVID injection was not reported (captured as unknown). This report was serious (Other Medically Important Condition).; Sender's Comments: This 52/53-year-old hypertensive male patient of unspecified ethnicity developed lower leg deep vein thrombosis (DVT) after 24 hours of receiving COVID-19 VACCINE AD26.COVID.S for the prevention of symptomatic SARS-CoV-2 virus infection. The was prior history of ""provoked"" DVT 10 years ago. No concomitant medications reported. The patient reported that D-Dimer was positive and ultrasound showed DVT. The patient was started on rivaroxaban. No other details reported. The information available precludes a complete and meaningful assessment. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information was requested.""</p>
COVID19 VACCINE	JANSSEN	1269940-1	40-49 years	Unknown	<p>BLOOD CLOT IN ARM; FEELING SICK; This spontaneous report received from a patient via a company representative concerned a 47 year old female. The patient's weight, height, and medical history were not reported. The patient was not pregnant at the time of report The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total, administered on 05-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date in APR-2021, the patient experienced burning sensation in arm, tenderness of arm, and pronounced veins on arm; also she was feeling sick. She saw the healthcare professional (HCP) after these symptoms. She was told about a blood clot (tenderness / burning sensation/ pronounced veins) in the arm. HCP recommended her taking aspirin and applying heat to the arm. Treatment medications (dates unspecified) included: acetylsalicylic acid. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clot in arm, and the outcome of feeling sick was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: This 47-year-old female patient reported burning sensation and tenderness in arm, pronounced veins in arm, and feeling sick after an unspecified duration from receiving COVID-19 VACCINE AD26.COVID.S for the prevention of symptomatic SARS-CoV-2 virus infection. HCP was consulted and was ""told"" about a blood clot and prescribed aspirin with advice to apply her to the arm. No other details reported. The information available precludes a complete and meaningful assessment. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information was requested.""</p>

COVID19 VACCINE	JANSSEN	1269942-1	40-49 years	Unknown	<p>CHEST PAIN (WHOLE CHEST HAD LOT OF PAIN)/THOUGHT THAT HE HAD HEART ATTACK; SHORTNESS OF BREATH/COULD NOT BREATHE; SEVERE CRAMPING IN LEFT SHOULDER AND UPPER BODY; DIFFICULTY IN STANDING; SINUS; THOUGHT THAT HE WAS ABOUT TO PASS OUT; BUNCH OF CLOTS IN THE BOTTOM SIDES OF BOTH LUNGS AND ON THE TOP OF ONE OF THE SIDES; BEGINNING STAGES OF PNEUMONIA ON BOTH LOBES OF THE LUNGS (COLLAPSED); CRAMPING IN CHEST; This spontaneous report received from a patient concerned a 44 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) frequency 1 total, dose was not reported, administered to left arm on 06-APR-2021 at 12 noon for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 6-APR-2021 at 12 noon, patient got vaccinated and was fine that day . Next morning on 07-APR-2021, patient woke up with sever cramping in same shoulder which he got the shot in, most pain was in the upper left quarter of his torso to down half way to chest up to the shoulder till the neck . By the end of the day it spread to his whole chest and upper body. Also he had shortness of breath ,could not breath .The cramping and shortness of breath came at same time. He took Advil and went along with his day . He took 3 tablet of Advil 200mg every 4-5 hours all day ( total of 3 dose that day) . By night time the case was progressively worse as the whole chest had a lot of pain . He thought that he had heart attack . He thought that he was about to pass out . He could not stand on his own . So his wife took him to emergency room at mid night at 12:30 am on 08-APR-2021. He stayed there for 5 hours and they did bunch of tests , EKG which rolled out the heart attack .They did Chest X-ray which found things then did D-dimer which its level was very high . They found bunch of clots in the bottom sides of both lungs and on the top of one of the sides. They did ultra sound on the legs which had no evidence of blood clots . They discharged him from the emergency room as they felt that he was ok to be out . After couple of hours after discharge , patient's health care professional wrote for him Eliquis, antibiotic and pain reliver. He was given antibiotic because he had beginning stages of pneumonia on both lobes of the lungs (collapsed) . It was found air sacs in lung with signs of pneumonia in both lobes . He came home and started to monitor his blood oxygen . He stayed in the same position till recovery . He was better each day since last week but still had sinus and cramping in the chest ( very minor but was still there). The lung capacity was very limited to take some steps. Patient stated that he needed a specialist to understand his condition. He had no medical history before that incidence . He was wondering regarding which type of blood thinner was good for this type of blood clots because he read that the regular blood thinners are not good for that type of blood clot which his HCP gave (regular blood thinner). Laboratory data included: Total lung capacity decreased (NR: not provided) lung capacity is very limited. On 08-APR-2021, Laboratory data included: Chest X-ray (NR: not provided) found things, EKG (NR: not provided) rolled out heart attack, Fibrin D dimer (NR: not provided) level was very high, and Ultrasound scan (NR: not provided) no evidence of blood clots. Treatment medications (dates unspecified) included: apixaban, and ibuprofen. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The</p>
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COVID19 VACCINE	JANSSEN	1269949-1	Unknown	Unknown	<p>BLOOD CLOTS IN THE BRAIN; EXTRAORDINARY PAIN; This spontaneous report received from a consumer via a company representative concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose, start therapy date were not reported,1 total, administered for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date in APR-2021, the patient had clots in the brain. The patient was flown to the hospital and had been in Intensive Care Unit (ICU) for the past 2 weeks from the report. The patient underwent multiple procedures for it, and was in extraordinary pain. The patient was currently receiving plasmapheresis. The number of days of hospitalization was not specified. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clots in the brain, and extraordinary pain. This report was serious (Hospitalization Caused/Prolonged).; Sender's Comments: V0: This female patient of unspecified age and ethnicity was reported to have been admitted in ICU for clots in the brain after an unspecified duration of receiving COVID-19 VACCINE AD26.COVS for the prevention of symptomatic SARS-CoV-2 virus infection. The patient underwent multiple unspecified procedures and currently undergoing plasmapheresis. No other details reported. The information available precludes a complete and meaningful assessment. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information was requested.</p>
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COVID19 VACCINE	JANSSEN	1269950-1	50-59 years	Unknown	<p>PULMONARY EMBOLISM; HAEMOPERITONEUM; MESENTERIC HAEMORRHAGE; SPLENIC HAEMORRHAGE; SPLENIC RUPTURE; SPLENIC THROMBOSIS; SPLENOMEGALY; LEFT UPPER QUADRANT/ABDOMINAL PAIN; DYSPNOEA; This spontaneous report received from a physician concerned a 53 years old female The patient's height, and weight were not reported. The patient had no known allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805029, and expiry: UNKNOWN) dose was not reported, 1 total administered on 16-MAR-2021 for prophylactic vaccination. Concomitant medications included Centrum Multi-Gummies for Women. On an unspecified date in MAR-2021 the patient began to experience slowly progressive shortness of breath; on 01-APR-2021 she had left upper quadrant pain. On 03-APR-2021 the patient presented to the emergency room. Laboratory data included: Pulmonary Angiogram/CT Chest - abnormal and computerised tomogram abdomen/pelvis at 09:37, showed segmental and subsegmental pulmonary emboli in the lower lobes of both lungs. Small volume perisplenic hemorrhage and small volume pneumoperitoneum in the pelvis or findings concerning for spontaneous splenic rupture and moderately enlarged spleen. Additional CT abdomen and pelvis with IV contrast at 23:05 showed: Small to moderate amount of hemoperitoneum, slightly increased since the earlier study. There is definitely new blood adjacent to the liver. The hemorrhage adjacent to the spleen appears similar to the earlier study. Due to the timing of the scans with relation to the contrast injection, the physician could not confirm a splenic laceration, although it was suspected to be the source of hemorrhage. Small amount of mesenteric blood was slightly increased. Continuous heparin infusion was started for bilateral pulmonary embolism. On 04-APR-2021, an inferior vena cava filter was placed and patient was vaccinated with Acthib (HIB Vaccine), Bexsero (meningococcal vaccine) and Prevnar (pneumococcal vaccine) in anticipation of splenectomy. On 07-APR-2021, a laparoscopic splenectomy was performed. The spleen was evaluated by pathology which reported that organizing blood clot on surface was consistent with rupture. No evidence of malignancy was reported. The patient was also treated with anticoagulant therapy (dates unspecified). The patient remained inpatient while recovering from surgery. On 12-APR-2021, the patient was transitioned to rivaroxaban for therapeutic anticoagulation. Patient remained hospitalized as of 12-APR-2021. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from pulmonary embolism, haemoperitoneum, mesenteric haemorrhage, splenic haemorrhage, splenic rupture, splenic thrombosis, splenomegaly, dyspnoea, abdominal pain upper, and left upper quadrant/abdominal pain. This report was serious (Hospitalization Caused / Prolonged, Disability Or Permanent Damage).; Sender's Comments: V0: This 53-year-old female patient of unspecified ethnicity was found to have pulmonary embolism and spontaneous splenic rupture 18 days after receiving COVID-19 VACCINE AD26.COVID2.S for the prevention of symptomatic SARS-CoV-2 virus infection. No concurrent illness and medical history reported. Emergency room consult for slowly progressive shortness of breath and left upper quadrant pain that starts on an unspecified date after vaccination. Pulmonary Angiogram/CT Chest showed segmental and subsegmental pulmonary emboli in the lower lobes of both lungs; small volume perisplenic hemorrhage and small volume pneumoperitoneum in the pelvis;</p>
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COVID19 VACCINE	JANSSEN	1269951-1	50-59 years	Unknown	<p>BLOOD CLOT IN UPPER THIGH; NO PULSE FROM KNEE DOWN ON RIGHT LEG; RINGING AND BUZZING IN EARS; PURPLE TOE; COULD NOT MOVE; FEELING CRAPPY; TIRED; NAUSEOUS; This spontaneous report received from a patient concerned a 58 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included Barrett's esophagus, and controlled high blood pressure. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular batch number: 1805031, and expiry: unknown) dose was not reported, 1 total administered in left arm on 24-MAR-2021 for prophylactic vaccination. Concomitant medications included Nexium (esomeprazole sodium) for Barrett's esophagus, and lisinopril for high blood pressure. On 25-MAR-2021, the day after the vaccination, patient felt crappy and could not move, had tiredness and nauseous. After 10 to 12 days of vaccination on an unspecified date in APR-2021, the patient had ringing and buzzing in ears, pain in the bottom of feet on walking, and purple discoloration to front of the right toe. The patient had visited health care professional (HCP). The patient had undergone some tests and HCP identified no pulse from the knee down on his right leg and a blood clot in upper thigh. The patient had experienced pins and needles and buzzing on his leg. He has also has a ringing and a buzzing in his ears and the bottom of his feet hurt when he walked on them. The patient was scheduled for an appointment with cardiovascular surgeon on 28-APR-2021, prior to the visit the patient has to tested negative for COVID. The patient went to take test on 23-APR-2021 and results not yet received. Laboratory data included: Peripheral pulse absent (NR: not provided) no pulse from the knee down on right leg. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the feeling crappy, tired, nauseous, no pulse from knee down on right leg, blood clot in upper thigh, ringing and buzzing in ears and could not move was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to. This spontaneous report received from a patient concerned a 58 year old male.; Sender's Comments: VO: This 58-year-old male patient was found to have blood clot in upper thigh with no pulse from the knee down 10 to 12 days after receiving COVID-19 VACCINE AD26.COV2.S for the prevention of symptomatic SARS-CoV-2 virus infection. Concurrent conditions include Barret's esophagus and ""controlled"" high blood pressure; concomitant medications includes Nexium and lisinopril. The symptoms reported were ringing and buzzing in ears, pain in the bottom of feet on walking, pins and needles and buzzing on his leg, and purple discoloration to front of the right toe that prompted consult with HCP, who advised the patient that there was no pulse from the knee down on his right leg and a blood clot in upper thigh. Prior COVID test was negative. No other details reported. The information available precludes a complete and meaningful assessment. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information was requested.""</p>
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COVID19 VACCINE	JANSSEN	1269952-1	50-59 years	Unknown	<p>BLOOD CLOT IN LEG; SHORTNESS OF BREATH; HEART RATE INCREASED; GANGRENE IN TOE; RIGHT LEG SWOLLEN; RIGHT FOOT SWOLLEN; CHILLS; RUNNY NOSE; FEELING HOT; This spontaneous report received from a patient concerned a 50 year old male. The patient's height and weight were not reported. The patient's concurrent conditions included high blood pressure and diabetes. The patient received COVID-19 vaccine Ad26.CoV2.S (suspension for injection, route of administration not reported, batch number 1802070, expiry date unknown), dose not reported, 1 total administered on 19-APR-2021 for prophylactic vaccination on left arm. Concomitant medications included amlodipine besilate for drug used for unknown indication, empagliflozin for drug used for unknown indication, fenofibrate for drug used for unknown indication, insulin aspart for drug used for unknown indication, insulin glargine for drug used for unknown indication, losartan for drug used for unknown indication, and pioglitazone hydrochloride for drug used for unknown indication. On an unspecified date (reported as 22-MAR-2021; 28 days prior to vaccination), the patient experienced shortness of breath, heart rate increased, runny nose, chills and was hospitalized (date unspecified). He reported that on this past Saturday, 17-APR-2021 (2 days prior to vaccination), he went to the emergency room. He reported that his toenails were coming off, the skin on his toes was coming off, and he had swelling in his right foot and up his leg. He says there was no circulation going to his toe and he was diagnosed with having a blood clot in his right leg. He says he had surgery to open up the arteries in his leg, and also reported gangrene in his toe. The subject was discharged on 21-APR-2021. On 23-APR-2021, the patient experienced feeling hot. He also reported that he may need to have his right pinky (fifth) toe amputated because it has gangrene. He reported that he is going to go back to the hospital, to which he would seek medical attention if he was having issues. Treatment medications (dates unspecified) included paracetamol. When called back due to his vaccination dates being after event start dates, the patient said that his memory is not too good, so he 'had to take his time to remember the correct dates'. The action taken with COVID-19 vaccine Ad26.CoV2.S was not applicable. The patient was recovering from blood clot in leg, and had not recovered from runny nose, shortness of breath, heart rate increased, chills, feeling hot, gangrene in toe, right leg swollen, and right foot swollen. This report was serious (caused hospitalization).; Sender's Comments: V0: This 50-year-old hypertensive and diabetic male patient reported that he was feeling hot and may need to have his fifth toe amputated because it has gangrene 4 days after receiving COVID-19 VACCINE AD26.COV2.S for the prevention of symptomatic SARS-CoV-2 virus infection and 2 days after discharge from the hospital. The patient was hospitalized for shortness of breath, heart rate increased, runny nose, and chills 28 days prior to vaccination. The patient went to the emergency room 2 days prior to vaccination because his toenails/skin on his toes were coming off, swelling in his right foot and up his leg, gangrene in his toe; he reported that there was no circulation going to his toe and was diagnosed with having a blood clot in his right leg; the patient reported he had surgery to ""open up"" the arteries in his leg. Four days after vaccination, the patient felt hot and reported reported that he may need to have his right pinky (fifth) toe amputated because it has gangrene. The patient is taking paracetamol as treatment. No</p>
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COVID19 VACCINE	JANSSEN	1269953-1	30-39 years	Unknown	<p>PULMONARY EMBOLISM IN CHEST; TIREDNESS; This spontaneous report received from the patient's mother concerned a 39 year old. The patient's weight was 251 pounds, and height was 66 inches. The patient's past medical history included a previous pulmonary embolism on 12-JUL-2012, which the reporter said the physician attributed to the patient being "obese and lays on her bed and doesn't exercise". Concurrent conditions included irregular menstruation, schizoaffective disorder, panic attacks, anxiety attacks, depression, incontinence, gastritis, constipation, sciatica nerve pain, asthma, obese, and doesn't comprehend well. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1802070 expiry: UNKNOWN) dose was not reported, 1 in total administered on 06-MAR-2021 at left arm for prophylactic vaccination. Non-Company suspect included ethinylestradiol/ferrous fumarate/norethisterone acetate, "for two months" for irregular menstruation. On 17-MAR-2021, the patient's physician ordered the patient to stop taking. Concomitant medications included salbutamol, lactulose for constipation, clozapine, gabapentin (noted as the doctor was trying to wean patient off medication), oxybutynin hydrochloride, pantoprazole, risperidone, valproate semisodium, vilazodone hydrochloride, and unspecified breathing treatments. In MAR-2021, the patient's mother stated that the first few days after vaccination the patient was fine. After a few days, patient was more tired than usual. On 16-MAR-2021, the patients mother noticed the patient's right leg was swollen and decided to take the patient to the Emergency Room. She was diagnosed with pulmonary embolism in the chest verified with radiology tests of chest and many other tests. Treatment included Eliquis 5 mg 2 times a day to treat the pulmonary embolism in her chest. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of pulmonary embolism in chest was not reported. The patient had not recovered from tiredness. This report was serious (Other Medically Important Condition); Sender's Comments: V0: This 39-year-old obese (BMI 40.5 kg/m2) female patient was diagnosed with pulmonary embolism 10 days after receiving COVID-19 VACCINE AD26.COVID.S for the prevention of symptomatic SARS-CoV-2 virus infection. Concurrent conditions includes irregular menstruation, schizoaffective disorder, panic attacks, anxiety attacks, depression, incontinence, gastritis, constipation, sciatica nerve pain, asthma, obese, difficulty in comprehension. Concurrent medications includes ethinylestradiol/ferrous fumarate/norethisterone acetate, salbutamol, lactulose, clozapine, gabapentin, oxybutynin hydrochloride, pantoprazole, risperidone, valproate semisodium, vilazodone hydrochloride, and unspecified breathing treatments. There was prior history of pulmonary embolism (PE) 9 years prior to vaccination and was advised to be due to obesity and lack of physical activity. Emergency room consult for leg swelling 10 days after vaccination; diagnosed with PE with radiology and many other unspecified tests; treated with Eliquis. Th event is confounded by increased risk with prior history of pulmonary embolism, obesity, OCP, and risperidone (class effect). The information available precludes a complete and meaningful assessment. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information was requested."</p>
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COVID19 VACCINE	JANSSEN	1269967-1	Unknown	Unknown	<p>A LEFT UPPER EXTREMITY DVT INVOLVING THE SUBCLAVIAN AND AXILLARY VEIN; LEFT UPPER ARM SWELLING; LEFT UPPER ARM PAIN; This spontaneous report received from a health care professional (nurse practitioner) and concerned a 74 year old male. The patient's height, and weight were not reported. The patient's past medical history included DVT (deep vein thrombosis) of lower extremity and was not on anticoagulation since and was treated with warfarin times 3 months only. The concurrent conditions included type 2 diabetes, chronic hypoxemic respiratory failure, chronic kidney disease, anemia, and hypertension. The patient was previously treated with warfarin. The patient received COVID-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1802070, and batch number: 1802070 expiry: 25-MAY-2021) dose was not reported, administered in left deltoid on 09-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 14-APR-2021, the patient developed a left upper extremity DVT involving the subclavian and axillary vein, left upper arm swelling and had left upper arm pain. On 19-APR-2021, the patient called and notified the office that the left arm was sore and swollen times 4-5 days. A registered nurse did a home visit on 20-APR-2021 and recommended an ultrasound to be done. On 26-APR-2021, the ultrasound confirmed a left upper extremity DVT involving predominantly the subclavian and axillary vein. On 26-APR-2021, Laboratory data included: CT Angiogram (to rule out pulmonary embolism) pending, COVID-19 virus test (NR: not provided) pending, Computerized tomogram thorax (NR: not provided) pending, Creatinine (NR: not provided) 1.59, ECG (Electrocardiogram) results not provided, Fibrin D dimer (NR: not provided) 3.95, Glomerular filtration rate (NR: not provided) 52, Hematocrit (NR: not provided) 33.2 %, Hemoglobin (NR: not provided) 10.4, International normalised ratio (NR: not provided) 2.8, NT-proBNP (NR: not provided) normal, Platelet count (NR: not provided) 309, and Prothrombin time (NR: not provided) 28.4. The patient was treated with rivaroxaban, 15 mg, oral, twice a day. The patient was currently in the emergency room with testing pending. The patient did not have other symptoms to report or note. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from left upper arm swelling, left upper arm pain, and a left upper extremity dvt involving the subclavian and axillary vein. This report was serious (Life Threatening).; Sender's Comments: V0: This 74-year-old male patient was found to have left upper extremity deep vein thrombosis (DVT) confirmed by ultrasound 17 days after receiving COVID-19 VACCINE AD26.CO2.S for the prevention of symptomatic SARS-CoV-2 virus infection. The patient has underlying type 2 diabetes, chronic hypoxemic respiratory failure, chronic kidney disease, anemia, and hypertension; the patient had prior history of DVT of lower extremity of unspecified date and was treated with warfarin for 3 months. No concomitant medications were reported. The symptom reported left upper arm pain and swelling 5 days after vaccination; persistence prompted consult with a registered nurse the recommended ultrasound; which revealed left upper extremity DVT involving predominantly the subclavian and axillary vein. Platelet count 309, Prothrombin time 28.4, INR 2.8, NT-proBNP normal, Fibrin D-dimer 3.95, GFR 52; awaiting result of CT and CT angiogram, COVID test, and ECG. The patient was treated with rivaroxaban. No other details reported. Based on the information that is available, the event is assessed as plausible with the causal</p>
COVID19 VACCINE	JANSSEN	1276388-1	Unknown	Unknown	<p>BLOOD CLOTS; SEVERE PAIN; This spontaneous report received from a consumer concerned a patient of unspecified sex and age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, the patient experienced blood clots and severe pain, and was hospitalized (date unspecified). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the blood clots and severe pain was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: This is a report of a patient, unspecified age, unspecified gender, unknown ethnicity, who was hospitalized for pain and blood clots on an unspecified number of days after receiving the covid-19 vaccine ad26.cov.2.s. The information provided precludes a meaningful medical assessment. Additional information requested.</p>

COVID19 VACCINE	JANSSEN	1276393-1	50-59 years	Unknown	<p>TACHYCARDIA; DRY MOUTH; DIZZINESS WITH STANDING AND INTERMITTENTLY WITH SITTING; PULMONARY EMBOLISM; FEELING OF DOOM/ FEELING OF PASSED OUT; FATIGUE; This spontaneous report received from a patient via a company representative via the VAERS (Vaccine Adverse Event Reporting System) concerned a 50 year old female unknown ethnicity . The patient's height, and weight were not reported. The patient's concurrent conditions included osteoarthritis, gluten intolerance, and diflucan allergy. The patient was previously treated with fluconazole. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805029, expiry: UNKNOWN) with unspecified dose on left arm, on 27-MAR-2021 11:00 for prophylactic vaccination. Concomitant medications included amino acids NOS, biotin, cannabidiol, collagen, ethinylestradiol/norethisterone acetate, and hyaluronic acid. On 07-APR-2021, the patient experienced dizziness with standing and intermittently with sitting, tachycardia, dry mouth, chest pressure, shortness of breath, and feeling of extreme doom. On an unspecified date, the patient was transported to the clinic. In the clinic the patient had heart rate of about 140 with irregular beats. The patient had undergone Electrocardiography test which showed ST Depression. The patient's symptoms were improved by taking nitroglycerin. As the clinic did not have the technology to provide care so the patient was emergently transported to the hospital. In the hospital the patient's D-dimer level was positive. Later the patient undergone Computerized Angiogram for lungs which showed pulmonary embolism. The patient undergone Dopplers studies of both legs which showed as negative. The patient had received Heparin treatment for several hours and then later switched to Eliquis. After 6 hours being on Eliquis treatment the patient had same original symptoms and for that again nitroglycerin was administered. The patient was placed back on heparin for a longer period of time. Later on the patient got switched to Eliquis 10 mg twice daily for 7 days and further to 5 mg twice daily for 6 to 9 months. The patient had undergone Angiogram of head and neck which was normal. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from tachycardia, feeling of doom/ feeling of passed out and dry mouth on APR-2021, had not recovered from fatigue, dizziness with standing and intermittently with sitting and pulmonary embolism. This report was serious (Hospitalization Caused / Prolonged, Other Medically Important Condition, and Life Threatening). Sender's Comments: V0 -covid-19 vaccine ad26.cov2.s-Pulmonary embolism , Feeling doom, Tachycardia, Dry mouth, Dizziness with standing, Fatigue This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>
COVID19 VACCINE	JANSSEN	1276394-1	40-49 years	Unknown	<p>LOSS OF BLOOD; VOMITING; BACK PAIN; ABDOMINAL PAIN; FEELING WEAK; HEADACHE; BLOOD CLOTTING; COULD NOT MOVE; ONLY COULD DO 5 MINUTES OF WORK; This spontaneous report received from a patient concerned a 45 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included fibroids. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1802070CCHD,expiry: UNKNOWN) dose was not reported,1 total administered on 20-MAR-2021 for prophylactic vaccination to left arm. No concomitant medications were reported. On 22-MAR-2021, the patient experienced blood clotting which lasted for three weeks and resolved as per physician on same day the patient experienced headache which got resolved on 22-Apr-2021. On 18-APR-2021, the patient experienced loss of blood, vomiting, back pain, abdominal pain and patient felt weak. On an unspecified date in 2021, the patient went to hospital, it was also reported that patient was not able to move and could do only 5 minutes of work. Patient got confused between clotting with menstruation. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from blood clotting on 12-APR-2021, and headache on 22-MAR-2021, was recovering from loss of blood, feeling weak, vomiting, back pain, and abdominal pain, and the outcome of could not move and only could do 5 minutes of work was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: In narrative of source document vaccination date is 20-Mar-2021 and in the structured field of source document vaccination date is 20-Apr-2021. So as per conservative approach, date given in narrative 20-Mar-2021 is taken as vaccination date. V0 20210440392-COVID-19 VACCINE AD26.CO2.S-Blood clotting and loss of blood. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY.</p>

COVID19 VACCINE	JANSSEN	1276398-1	40-49 years	Unknown	<p>POSSIBLE BLOOD CLOT; INCREASED HEART RATE; CHEST TIGHTNESS; HIGH BLOOD PRESSURE; NECK PAIN; ARM PAIN; HEAD PAIN; BODY SHAKING; CHILLS; HIP JOINT PAIN; BACK PAIN; This spontaneous report received from a patient concerned a 48 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included high blood pressure, osteoarthritis, fibromyalgia, non smoker, and non alcohol user. The patient experienced drug allergy when treated with diphenhydramine hydrochloride. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805022) dose was not reported, 1 total, administered on right arm on 14-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 14- MAR-2021, around 9 pm the patient experienced body shaking, and chills for which she took Theraflu. On 15-MAR-2021, morning the patient experienced high blood pressure, chest tightness and increased heart rate of 156 BPM for which she went to the ER. She also experienced neck pain, arm pain and head pain. lung and chest examination was normal. Laboratory data included: Blood pressure (NR: not provided) increased, Fibrin D dimer (NR: not provided) 780, and Heart rate (NR: not provided) 156 pm. As the- d dimer test result was high, the doctor said she has a blood clot. She was given a shot of Toradol at the ER. On 17-MAR-2021, Laboratory data included: Fibrin D dimer (NR: not provided) 650. On 30-MAR-2021, She had another episode, she was in a lot of pain. She went back to ER. Laboratory data included: CAT scan (NR: not provided) normal. They sent her home and prescribed her Meloxicam. The patient went to see her Cardiologist after that, She stated that her cardiologist didn't do any blood work or mention anything regarding a blood clot. Treatment medications (dates unspecified) included: ketorolac tromethamine, acetylsalicylic acid, meloxicam, and dextromethorphan. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from high blood pressure, chest tightness, increased heart rate, body shaking, chills, and head and neck pain and arm pain on MAR-2021, had not recovered from hip joint pain, back pain, and the outcome of blood clot was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:-covid-19 vaccine ad26.cov2.s-possible blood clot. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>
COVID19 VACCINE	JANSSEN	1276409-1	Unknown	Unknown	<p>BLOOD IN URINE; BLOOD CLOTS IN URINE; SLEEPY; SORE ARM; This spontaneous report received from a patient concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1808609, expiry: 09-Jun-2021) dose was not reported, administered on 30-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 31-MAR-2021, the patient got the shot experienced sore arm. On 01-APR-2021, at morning he was very sleepy. On 21-APR-2021, the patient went to the bathroom he had blood in urine and again he noticed there were some clots in the urine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from sore arm, and sleepy, and had not recovered from blood in urine, and blood clots in urine. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:-Covid-19 vaccine ad26.cov2.s.Blood dot in urine and blood in urine. This event is considered unassessable. The event has an unknown/undear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p>



COVID19 VACCINE	JANSSEN	1276430-1	Unknown	Unknown	RARE BLOOD CLOT; LOW PLATELETS; This spontaneous report received from a consumer concerned about 50 years old female. The reporter obtained the information from news/media. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total administered on APR-2021 for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unknown date in APR-2021 after vaccination, the patient experienced severe headache, abdominal pain, leg pain and shortness of breath. The patient developed a rare blood dot and low platelets on an unspecified date in APR-2021, within two weeks of receiving JANSSEN COVID-19 vaccine. The patient was hospitalized on an unspecified date in APR-2021. On APR-2021, the patient died from blood clot. The reporter was not sure whether the events was related to the vaccination. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of rare blood clot on APR-2021, and had not recovered from low platelets. This report was serious (Death, and Hospitalization Caused / Prolonged); Sender's Comments: V0: This female patient in her 50s was reported to have developed a rare blood clot and low platelets within two weeks of receiving JANSSEN COVID-19 vaccine. On an unspecified date, symptoms reported were severe headache, abdominal pain, leg pain and shortness of breath. The patient was hospitalized on an unspecified date and subsequently died from blood clot. It was not known if autopsy was performed. No other details reported. The information available precludes a complete and meaningful assessment. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded.; Reported Cause(s) of Death: BLOOD CLOT
COVID19 VACCINE	JANSSEN	1276432-1	Unknown	Unknown	BLOOD CLOTTING; This spontaneous report received via traditional media from a patient concerned an adult female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown and expire date: Unknown ) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient experienced blood clotting and was hospitalized (date unspecified). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clotting was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition); Sender's Comments: V0: 20210447114-Covid-19 vaccine ad26.cov2.s- BLOOD CLOTTING These events are considered unassessable. The events have a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the events.
COVID19 VACCINE	JANSSEN	1276433-1	Unknown	Unknown	BLOOD CLOTS; This spontaneous report received via social media/news from a patient concerned an adult female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, 1 in total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient had clot blood and was hospitalized. The symptoms appeared were found to be consistent with the six cases reported elsewhere last week. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clots was not reported. This report was serious (Hospitalization Caused / Prolonged); Sender's Comments: V0: -Covid-19 vaccine ad26.cov2.s-Blood clot. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.

COVID19 VACCINE	JANSSEN	1276435-1	50-59 years	Unknown	RIGHT LEG DEEP VEIN THROMBOSIS; PERIPHERAL VEIN OCCLUSION; This spontaneous report received from a patient via VAERS (Vaccine Adverse Event Reporting System) (VAERS ID: 1201107) concerned a 54 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included penicillin allergy, and chronic obstructive pulmonary disease. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805031 expiry: UNKNOWN) dose was not reported, administered on 12-MAR-2021 for prophylactic vaccination. Concomitant medications included ferrous sulfate, ipratropium bromide/salbutamol sulfate, montelukast, salbutamol sulfate, budesonide, ipratropium, olodaterol hydrochloride/tiotropium bromide monohydrate and prednisone for chronic obstructive pulmonary disease. On 07-APR-2021, the patient experienced right leg deep vein thrombosis. Patient was hospitalized for 4 days. On 07-APR-2021, the patient experienced peripheral vein occlusion. On 07-APR-2021, the patient had ultrasound scan abnormal. Laboratory data included: Ultrasound Doppler (NR: not provided) unknown, and right leg duplex Ultrasound Scan confirms right leg occlusive DVT involving common femoral, superficial femoral, and popliteal vein. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from right leg deep vein thrombosis, and peripheral vein occlusion. This report was serious (Hospitalization Caused / Prolonged); Sender's Comments: V0: 20210447773-Covid-19 vaccine ad26.cov2.s-Right leg deep vein thrombosis. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the events.
COVID19 VACCINE	JANSSEN	1276474-1	Unknown	Unknown	PULMONARY EMBOLISM; This spontaneous report received from a consumer concerned a multiple females patient's of unspecified age. The patient's weight, height, and medical history were not reported. The patient's received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number: Unknown) dose, 1 total start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date after vaccination, the patient's experienced pulmonary embolism. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of pulmonary embolism was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210446568.; Sender's Comments: V0: 20210450133-JANSSEN COVID-19 VACCINE Ad26.COVID-19 Pulmonary embolism. This event is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.
COVID19 VACCINE	JANSSEN	1276477-1	65+ years	Unknown	DIARRHEA; LETHARGIC; GENERALISED ACHING; HEADACHE; SWELLING AT INJECTION SITE; REDNESS AT INJECTION SITE; BLOOD CLOT FROM THIGH TO CALF; This spontaneous report received from a consumer concerned a 66 year old male. The patient's height, and weight were not reported. The patient's concurrent conditions included paralyzed on left side from a previous injury and not very active. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered 1 total administered on 06-APR-2021 on right arm for prophylactic vaccination. The batch number was not reported and it has been requested. No concomitant medications were reported. On 07-APR-2021, the patient had blow-out diarrhea, lethargic, body aches, headache. On APR-2021, the patient experienced leg pain (started week ago), swelling at injection site and redness at injection site. His left foot was swollen, and called physician to check for blood clot or break. The doctor said that the test showed a blood clot from his thigh all the way down to his calf that was a medical emergency. Reporter thinks there was a possibility that they were already exposed to COVID. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot from thigh to calf, diarrhea, lethargic, generalised aching, headache, swelling at injection site and redness at injection site was not reported. This report was serious (Other Medically Important Condition); Sender's Comments: V0. 20210450241- COVID-19 VACCINE Ad26.COVID-19 S -Blood clot. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

COVID19 VACCINE	JANSSEN	1276478-1	Unknown	Unknown	BLOOD CLOT; This spontaneous report received from a consumer via news concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration was not reported, batch number: unknown) dose, start therapy date were not reported, 1 total, for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient developed a blood clot. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Other Medically Important Condition); Sender's Comments: V0: -Blood clot. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
COVID19 VACCINE	JANSSEN	1276487-1	Unknown	Unknown	STROKE/HEADACHE; BLOOD CLOT; INJECTION SITE REACTION; PAIN IN ARM; This spontaneous report received from a patient concerned a 79 year old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805020, expiry: UNKNOWN) dose was not reported, administered to left arm on 11-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 25-MAR-2021, 2 weeks after receiving the vaccination, the patient stated his injection site on his left arm ""felt horrible"" ""like someone was stabbing him in that joint"" (both events captured as injection site reaction). The patient reported his doctors did not know what was causing this and he could not get rid of it. On an unspecified date the patient experienced headaches with one being described as going from the back of his head to his left temple, he reported not usually having headaches. The patient also experienced severe pain when moving left arm with pain worsening at night when not moving. The patient was unable to reach up to grab things. On 24-APR-2021, the patient was taken to the hospital and was diagnosed as had a stroke. On an unspecified date results of Magnetic Resonance Imaging (MRI) were 'blood clots in the artery that goes up middle of spine and back of neck. The patient stated the results also had ""right side numbness, vertigo, slurred speech"". Results of Computerised Tomogram (CT) (date unspecified) were per the patient ""internal carotid arteries demonstrated calcified plaque, stenosis, arteries demonstrate localized three-four segment of left local artery"". The patient was discharged on an unspecified date and had not seen his regular physician yet. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the stroke, blood clot, injection site reaction, pain in arm and headache was not reported. This report was serious (Hospitalization Caused / Prolonged); Sender's Comments: V0 -covid-19 vaccine ad26.cov2.s-Stroke/Blood clot. This case concerns a patient of 79 year old male. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).""

COVID19 VACCINE	JANSSEN	1276504-1	Unknown	Unknown	<p>TRANSIENT ISCHEMIC ATTACK MORE FREQUENT; POSSIBLE BLOOD CLOT; SHORTNESS OF BREATH; CHEST PAIN; SWELLING IN ONE LEG; PULSATING HEADACHE; This spontaneous report received from a patient via social media concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose, 1 in total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, after took vaccine the patient had major health problems which was described as transient ischemic attack which was more frequent and lasted longer, headaches were a pulsating headache, shortness of breath(more than usual),chest pains, swelling in one leg and seems to be blood clots. The patient was enquire about the involvement of people in vaccine study with conditions like hepatitis C, strokes, chronic obstructive pulmonary disease, chronic headaches, liver problems, transient ischemic attack. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the transient ischemic attack more frequent, pulsating headache, shortness of breath, chest pain, swelling in one leg and possible blood clot was not reported. This report was serious (Other Medically Important Condition); Sender's Comments: V0-20210452291JANSSEN COVID-19 VACCINE Ad26.COV2.S This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p>
COVID19 VACCINE	JANSSEN	1276515-1	Unknown	Unknown	<p>CLOT IN LEGS; ESCALATING PAIN IN LOWER BACK; ESCALATING PAIN IN LEG; This spontaneous report received from a patient via news story concerned a 4 decade (early 40s) male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose was not reported, 1 total, administered on 08-APR-2021 for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. In APR-2021, the patient experienced clot in legs and was hospitalized. The patient was improving and scheduled to leave the hospital in few days. On 16-APR-2021, the Patient experienced escalating pain in lower back and leg. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from clot in legs, and the outcome of escalating pain in lower back and escalating pain in leg was not reported. This report was serious (Hospitalization Caused / Prolonged); Sender's Comments: V0: - Clot in legs (PT-Thrombosis). This event is considered unassessable. The event has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p>
COVID19 VACCINE	JANSSEN	1276518-1	40-49 years	Unknown	<p>PROFOUND BLEEDING; CLOTTING; SUSPECT DYSFIBRINOGENEMIA; This spontaneous report received from a health care professional via a Regulatory Authority and concerned a 48 year old, female. The patient's height, weight and medical history were not reported. The patient was not pregnant at the time of reporting. The patient had no other illness at the time of vaccination, no chronic or long-standing health conditions, the patient was healthy without history of dysfibrinogenemia. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805020, and expiry: UNKNOWN) dose was not reported, administered on 09-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 22-MAR-2021, the patient experienced profound bleeding, and clotting and was suspected to have dysfibrinogenemia. The patient was currently hospitalized for the events (date unspecified). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from profound bleeding, clotting, and suspected dysfibrinogenemia. This report was serious (Hospitalization Caused / Prolonged, Other Medically Important Condition, and Life Threatening). Sender's Comments: V0:-covid-19 vaccine ad26.cov2.s -profound bleeding, clotting, suspect dysfibrinogenemia. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

COVID19 VACCINE	JANSSEN	1276519-1	60-64 years	Unknown	<p>PULMONARY EMBOLISM/RIGHT SIDED MID BACK PAIN; This spontaneous report received from a health care professional concerned a 64 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included Crohn's disease. The patient was previously treated with infliximab for Crohn's disease. The patient experienced drug allergy when treated with infliximab (Remicade). The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 042A21A, expiry: unknown) dose was not reported, 1 total administered on 31-MAR-2021 to left arm for prophylactic vaccination. Concomitant medications included vitamins nos, azathioprine, dicycloverine, and mesalazine for drug used for unknown indication. On 22-APR-2021 by evening, the patient experienced right-sided mid-back pain and shortness of breath and was presented to ED (emergency department) on 23-APR-2021. The patient's pain was sharp and worsened with coughing and deep inspiration; she felt that she was taking shallow breaths. Upon ED (emergency department) presentation, there was no shortness of breath, chest pain, dizziness, fevers, dysuria, or abdominal pain. The patient had reproducible pain on her right mid-back area. There was some mild diffuse tenderness in her abdomen, but it was reported that she always had a tender abdomen due to Crohn's disease. The patient had no peritoneal signs and had no recent travel history. On 23-APR-2021, the CTA (Computed tomography angiography) of chest was done with and without contrast and found out central and peripheral pulmonary emboli in the right lower lobe. The patient had no CT (computerized tomography) evidence of right heart strain. The patient's ground glass opacities within the right lower lobe was somewhat band like in appearance and concerned for early pulmonary infarcts. It was reported that this might also relate to sub segmental atelectasis or less likely an inflammatory/infectious process. The patient had also small right pleural effusion; no acute inflammatory process in the abdomen or pelvis. On 23-APR-2021, the patient's platelet count was 252 k/mcl and was tested negative for covid test. The patient was diagnosed with pulmonary embolism; she consulted hematology/oncology specialist and recommended with initiation of argatroban for treatment of pulmonary embolism. The patient was admitted to inpatient on 23-APR-2021. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of pulmonary embolism/right sided mid back pain was not reported. This report was serious (Hospitalization Caused / Prolonged); Sender's Comments: V0;-covid-19 vaccine ad26.cov2.s-Pulmonary Embolism. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>
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COVID19 VACCINE	JANSSEN	1276523-1	50-59 years	Unknown	<p>PULMONARY EMBOLISM; SHORTNESS OF BREATH; MIGRAINE HEADACHE; ELEVATED BLOOD PRESSURE; NAUSEA; FATIGUE; DIZZINESS; This spontaneous report received from a patient concerned a white 56 year old female. The patient's weight was 185 pounds, and height was 67 inches. The patient's past medical history included minor surgery on 14-APR-2021 to have a cyst removed from knee. The patient had a thyroidectomy in 1997 or 1998. Concurrent conditions included migraines when she was a child (only has 1 to 2 migraine a year), allergy to penicillin, social alcohol drinker, and was non smoker. The had no history of drug abuse or illicit drug usage. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 043A21A, expiry: UNKNOWN) dose was not reported, administered on 07-APR-2021 at left arm for prophylactic vaccination. No concomitant medications were reported. On 13-APR-2021, the patient experienced shortness of breath, dizziness, nausea, and fatigue. On 14-APR-2021, the patient experienced elevated blood pressure. On 17-APR-2021, the patient experienced pulmonary embolism and was hospitalized. Blood pressure was measured at 199/98 (approximately); blood test revealed ""some kind of count from heart being elevated"" and CT (computed tomogram) revealed multiple blood clots in both lungs. On 18-APR-2021 was admitted into the ICU (intensive care unit) and on the same day also experienced migraine headaches. On 19-APR-2021, a diagnostic ultrasound was negative for clots. At 17:00 the patient was discharged. Patient was hospitalized for 3 days. On 20-APR-2021, magnetic resonance imaging (MRI) and magnetic resonance venography (MRV) were performed by her pulmonologist, results not provided. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient recovered from shortness of breath, dizziness, and nausea on 20-APR-2021, and migraine headache on 22-APR-2021, had not recovered from pulmonary embolism, and fatigue, and the outcome of elevated blood pressure was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0 20210453258-COVID-19 VACCINE AD26.COV2.S-Pulmonary embolism and shortness of breath. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).""</p>
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COVID19 VACCINE	JANSSEN	1276526-1	65+ years	Unknown	<p>BLOOD CLOT WITH DYING PAIN IN RIGHT SHOULDER; This spontaneous report received from a patient concerned a 72 year old female. The patient's weight was 141 pounds, and height was 164 centimeters. The patient's concurrent conditions included back pain, two cysts on kidney, high blood pressure, anxiety, high cholesterol, non smoker, non alcoholic, and spine issue, and other pre-existing medical conditions included it was unknown that patient had drug abuse or illicit drug usage. she was health healthy and always doing exercises, she lifts 3kg dumbbells and walked and use indoor bicycle for exercise. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029, expiry: UNKNOWN) dose was not reported, frequency one total administered on 15-MAR-2021 for prophylactic vaccination. Concomitant medications included ditalopram for anxiety, lorazepam for anxiety, oxycodone for back pain, and spine issue, and acetylsalicylic acid for drug used for unknown indication. Patient received vaccine on March 15, 2021 at a local vaccination center. she woke up with pain and had this for several days before. somebody suggested going to the Emergency room. Patient proceeded to ER on 26-March-2021 and was seen by Doctor. Doctor suspected a blood clot and told the if its blood clot it could moved to lung and cause stroke. The patient reports the following tests were performed X-ray, ultrasound and blood tests. Test results all showed blood clot that the patient describes as deep vein in the right shoulder between shoulder and neck. Patient reported that she was given a blood thinner in her tummy and then a prescription for 30 days of Eliquis 5mg. Patient reported that the pain was killing her and stated she was dying of pain. The pain was in the area of the blood clot (right shoulder). Patient was also seen by a specialist who prescribed Eliquis prescription for 1 year. she was taking baby aspirin which told to continued. she finished her 30 days prescription ,she planning to visit ER as pain had not go away. She has been told not to stop the blood thinner as it is dangerous. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clot, and dying of pain s in the area of the blood clot (right shoulder). This report was serious (Other Medically Important Condition).; Sender's Comments: V0: 20210453704-COVID-19 VACCINE AD26.COV2.S - BLOOD CLOT WITH DYING PAIN IN RIGHT SHOULDER. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p>
COVID19 VACCINE	JANSSEN	1276530-1	40-49 years	Unknown	<p>DEATH; BLOOD CLOT; This spontaneous report received from a consumer news/social media platform concerned a 5 decade old female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient developed a rare blood clot and died within two weeks of getting the Janssen covid vaccine. On an unspecified date, the patient died from unknown cause of death. It was unknown whether autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Death, and Other Medically Important Condition). This case, from the same reporter is linked to.; Sender's Comments: V0-covid-19 vaccine ad26.cov2.s-This case concerns with 5 decade old female. Death, Blood clot. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s); Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH</p>

COVID19 VACCINE	JANSSEN	1276539-1	Unknown	Unknown	BLOOD CLOT; This spontaneous report received from a patient concerned an adult female. This report was received from news/social media platform reported by a consumer/other non health care professional. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 2021 for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date in APR-2021, after vaccination the patient experienced blood clot, and was hospitalized (date unspecified). This report was notified through VAERS on 22-APR-2021. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Hospitalization Caused / Prolonged). This case, from the same reporter is linked to 20210453777.; Sender's Comments: V0: 20210454136-COVID-19 VACCINE AD26.COVS.S - BLOOD CLOT. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.
COVID19 VACCINE	JANSSEN	1276543-1	50-59 years	Unknown	BLOOD CLOTS IN THE LUNGS; CHEST PAIN; SHORTNESS OF BREATH; This spontaneous report received from a patient concerned a 52 year old of unspecified sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) dose was not reported, administered on 06-APR-2021 for prophylactic vaccination in the left arm. The batch number was not reported and has been requested. No concomitant medications were reported. On 17-APR-2021, the subject experienced chest pain and shortness of breath and was taken to the Emergency Room. The patient was hospitalized and a diagnosis of blood clots in the lungs was made. The patient was hospitalized for 4 days. Corrective treatment included blood thinners ( to be taken for 6 months) and a follow-up appointment with the pulmonologist was scheduled. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the blood clots in the lungs, chest pain and shortness of breath was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: V0: 20210454248-Covid-19 vaccine ad26.cov2.s-Blood clots in the lungs, chest pain and shortness of breath. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
COVID19 VACCINE	JANSSEN	1276544-1	Unknown	Unknown	BLOOD CLOT IN BRAIN; This spontaneous report received from a consumer concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported, 1 total for prophylactic vaccination. The batch number was not reported. Per procedure, no follow up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient experienced blood clot in brain. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot in brain was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210453717.; Sender's Comments: V0:20210454254-covid-19 vaccine ad26.cov2.s-blood clot in brain. This event(s) is considered related. The event(s) has an unknown/undear temporal relationship, is unlabeled, and has unknown scientific plausibility. There are no other factors more likely to be associated with the event(s) than the drug.

COVID19 VACCINE	JANSSEN	1276549-1	50-59 years	Unknown	<p>LEFT SIGMOID SINUS VEIN THROMBOSIS; PORTAL VEIN THROMBOSIS; SPLENIC VEIN THROMBOSIS; SUPERIOR MESENTERIC VEIN THROMBOSIS; LEFT INTERNAL JUGULAR VEIN THROMBOSIS; THROMBOCYTOPENIA; ABDOMINAL PAIN; HEADACHE; This spontaneous report was received from a physician and concerned a 58-year-old white female. Initial information was received on 27-APR-2021, with additional information obtained via telephone follow up from the physician on 29-APR-2021. The patient's specific height and weight were not reported. The patient's past medical history included fatty liver, and the patient was overweight. Family history was significant for a deep venous thrombosis treated with anticoagulants in the patient's mother, and a history of unspecified blood clots in her maternal grandmother. The patient was on no medications, including no estrogen containing pharmaceutical products or supplements. She has never been exposed to heparin. The patient had no history of COVID-19 infection. The patient received COVID-19 VACCINE AD26.COV2.S (suspension for injection, route of administration not reported, batch number not reported) on 12-APR-2021. The batch number has been requested. No concomitant medications were reported. On 18-APR-2021, 6 days after receiving vaccine, the patient developed a headache. On 23-APR-2021, 11 days after receiving vaccine, the patient presented to the hospital with complaints of headache and abdominal pain. COVID test in the emergency room was negative. On 23-APR-2021, imaging of the head and abdomen revealed: left sigmoid sinus vein thrombosis, portal vein thrombosis, splenic vein thrombosis, superior mesenteric vein thrombosis, left internal jugular vein thrombosis. The patient also had thrombocytopenia, with platelet count on presentation 22,000 (units not provided). D-dimer was elevated at &gt;12.8 (units not provided), Fibrinogen was low at 103 (units not provided), HIT antibody test by ELISA was positive, and physicians made the diagnosis of Vaccine-induced Thrombotic Thrombocytopenia (VITT). The patient was hospitalized in the intensive care unit. Treatment medications included argatroban, steroids and IVIG. Following treatment, the platelet count remained low, with a nadir of 17,000. On 27-Apr-2021, she underwent thrombectomy and thrombolysis of the intra-abdominal clots. This was performed due to the potential for portal hypertension in the future, given the extent of the thromboses. Repeat CT venogram of the head on an unknown date, revealed resolution of the sigmoid sinus vein thrombosis; the internal jugular thrombosis persisted. The patient has steadily improved since the thrombectomy. Abdominal pain and headache are improving. Platelet count has steadily risen, to 138,000 on 29- Apr-2021. Her transaminases were slightly elevated on admission and have not worsened, and she appears to have no organ dysfunction. A dialysis catheter had been placed in the event she would require plasmapheresis, but this was never used. Additional laboratory data included: IgG and IgM antibodies against the SARS-COVID-2 nucleocapsid protein positive; Protein C deficiency negative; Protein S deficiency negative; Homocysteine level (NR: not provided) negative. Serotonin release assay, anticardiolipin panel and Factor V Leiden tests were pending. The plan was to transition the patient to an oral anticoagulant and remove the dialysis catheter on 30-APR-2021, with a possible discharge on 01-MAY-2021. The patient had not recovered from left sigmoid sinus vein thrombosis, portal vein thrombosis, splenic vein thrombosis, superior mesenteric vein thrombosis, and left internal jugular</p>
COVID19 VACCINE	JANSSEN	1276551-1	Unknown	Unknown	<p>BLOOD CLOTS; This spontaneous report received from a consumer (source: news report) concerned a female of age under 60. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry: unknown) dose, start therapy date were not reported, 1 total administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case No concomitant medications were reported. It was reported from a news story that, on an unspecified date, the patient experienced blood clots which was in investigation by an agency. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clots was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210454646.; Sender's Comments: V0:20210454446-covid-19 vaccine ad26.cov2.s- Blood clots. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

COVID19 VACCINE	JANSSEN	1276556-1	Unknown	Unknown	BLOOD CLOT; This spontaneous report received from a consumer concerned an adult male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) 1 total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient experienced blood clot. The reporter stated that as per news report, the agency was investigating this case of blood clot. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210454446.; Sender's Comments: V0:20210454646-covid-19 vaccine ad26.cov2.s -blood clot. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
COVID19 VACCINE	JANSSEN	1276561-1	65+ years	Unknown	DEEP VEIN THROMBOSIS IN RIGHT LEG (PAIN AND SWELLING); This spontaneous report received from a physician concerned a 69 year old White and not Hispanic or Latino male. The patient's height, and weight were not reported. The patient's concurrent conditions included arterial fibrillation, and sedentary lifestyle. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, and batch number: 207A21A expiry: 23-JUN-2021) dose was not reported, frequency 1 total, administered on 11-APR-2021 at left arm for prophylactic vaccination. Concomitant medications included apixaban for chronic atrial fibrillation. It was stated by internist that, on 26-APR-2021, the patient experienced deep vein thrombosis in right leg with symptoms pain and swelling, and was hospitalized on unspecified date. On unspecified date doctor was screening patient for covid-19 infection. On 27-APR-2021, Laboratory data included: Platelet count (NR: not provided) 167000. Laboratory data (dates unspecified) included: Duplex ultrasound (NR: not provided) definite clot in right leg. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of deep vein thrombosis in right leg (pain and swelling) was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition).; Sender's Comments: V0: 20210455157-JANSSEN COVID-19 VACCINE Ad26.COVID.S- Deep vein thrombosis. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY, UNDERLYING DISEASE.
COVID19 VACCINE	JANSSEN	1276566-1	Unknown	Unknown	BLOOD CLOT; SEVERE HEADACHE/ FEEL LIKE A CAP ON HER HEAD; This spontaneous report received from a consumer concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient experienced blood clot, and severe headache/ felt like a cap on her head. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the severe headache/ feel like a cap on her head and blood clot was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0: AER 20210455412-Covid-19 vaccine ad26.cov2.s-BLOOD CLOT. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

COVID19 VACCINE	JANSSEN	1276570-1	Unknown	Unknown	MID-STROKE; BLOOD CLOTS IN BRAIN; POST STROKE DEPRESSION; CANE USER; This spontaneous report received from a consumer (sister) concerned a 69 year old female. The patient's weight, height, and medical history were not reported. Patient was a completely healthy woman and was not on any medications. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) frequency once total, dose, start therapy date was not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient suffered a mid-stroke. Stroke showed that she suffered from blood clots in her brain. All of this happened after receiving Janssen vaccine. Patient had to walk with a cane (coded as cane user) and had been prescribed medication. Patient had to deal with other issues including depression (coded as post stroke depression) because of her new life long issues. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the mid-stroke, blood clots in brain, cane user and post stroke depression was not reported. This report was serious (Other Medically Important Condition); Sender's Comments: V0:2021045571-Covid-19 vaccine.ad26.cov2.S-Mid-stroke,Blood clots in Brain,Post stroke depression. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
COVID19 VACCINE	JANSSEN	1276571-1	Unknown	Unknown	THROMBOSIS (RED PATCHES ON HANDS, ARMS, LEGS AND FEET); SEVERE MIGRAINES; SEVERE VACCINATION REACTION; This spontaneous report received from a patient via a company representative concerned a 3 decade old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown and expiry date: Unknown) dose, 1 total administered, start therapy date was not reported for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. The patient had a severe vaccination reaction, experienced red patches on hands, arms, legs and feet. The patient had visited the hospital and was diagnosed with thrombosis by the physician. Patient was monitored and later discharged. The patient had reattended hospital for severe migraines, also had contacted centers for disease control and prevention regarding vaccination reaction. The patient was unknown for company representative and had only this information. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the thrombosis (red patches on hands, arms, legs and feet), severe migraines and severe vaccination reaction was not reported. This report was serious (Hospitalization Caused / Prolonged); Sender's Comments: V0.20210455657- COVID-19 VACCINE Ad26.COVID. S -Thrombosis, severe migraines , severe vaccination reaction. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

COVID19 VACCINE	JANSSEN	1276626-1	40-49 years	Unknown	<p>DEEP VEIN THROMBOSIS; This spontaneous report received from a consumer concerned a 49 year old male. The patient's weight was 80.3 kilograms, and height was 182.9 centimeters. The patient's past medical history included post-operative deep vein thrombosis (more than 30 years ago), depression, heart murmur, and back surgery, and his concurrent conditions included non-smoker, no alcohol use, and marijuana abuse. The patient had no history of known allergies. The patient's mother had a history of aneurysm. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, and expiry date: unknown) dose was not reported, administered on 08-APR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. Concomitant medications included fexofenadine hydrochloride (Allegra) for allergy, rivaroxaban (Xarelto) for venous thromboembolism, and omeprazole (Prilosec) for unknown indication. About one and half weeks after vaccination, on 21-APR-2021, the patient was taken to the emergency department and was admitted with the complaints of leg pain since 2 days with suspected blood clot in leg. Over the last days, patient's left leg looked swollen compared to the right leg. The patient also had pain, initially started in groin area and radiated down across the anterior portion of the leg, then to posterior leg, and into toes. The patient also had some intermittent tingling in toes. The patient denied of weakness, numbness or persistent paresthesia. The patient was concerned regarding the pain as it felt similar to the post-operative deep vein thrombosis he had in the past. The patient had been anxious since vaccination when hearing about the development of blood clots. The patient also denied of fevers, chills, chest pain, shortness of breath abdominal pain, nausea, vomiting, diarrhea, and difficulty walking. On 21-APR-2021 16:25, the patient's laboratory data included: Blood pressure (148/66 mmHg), Body mass index (24), Body temperature (98.8 F), Oxygen saturation (100 %) Pulse rate (88), and Respiratory rate (16). On 21-APR-2021 16:32, laboratory data included: Blood pressure (148/66 mmHg), Body temperature (97.8 F), Oxygen saturation (100 %), Pulse rate (91), and Respiratory rate (15). Other general physical examinations included: General: Well-developed well-nourished in no acute distress. HEENT (Head, Eye, Ear, Nose, Throat) examination: normocephalic atraumatic extra ocular motions are intact. Neck examination: Supple without jugular vein distention or meningismus. Lung examination: Clear auscultation bilaterally without wheezes rales or rhonchi. Heart examination: Regular rate and rhythm without murmurs rubs or gallops. Abdomen examination: Soft no tender non-distended without rebound or guarding. Extremities: Without clubbing cyanosis edema, no lacerations or abrasions or ecchymosis noted, no appreciable size difference in the left leg compared to the right, the patient had some tenderness throughout palpation of the medial thigh on the left with radiation up into the left inguinal region, no calf tenderness or swelling, no erythema, palpable posterior tibialis pulse. Skin examination: Warm and dry and well perfused. Psych examination: Appropriate mood and affect. Neuro examination: Cranial nerves 2-12 are grossly intact, strength is 5/5 in upper and lower extremities, full distal sensation in the left lower extremity, full plantar and dorsiflexion of the left foot including the left great toe, sensation is grossly intact, awake, alert and oriented x3. On ultrasound Doppler venous lower extremity test, identified sub occlusive thrombus in the left</p>
COVID19 VACCINE	JANSSEN	1276632-1	Unknown	Unknown	<p>CLOTS; This spontaneous report received from a physician concerned a male of unspecified age. The patient's weight, height and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: Unknown) frequency one total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. The physician reported that on an unspecified date, the patient experienced clots. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of clots was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210456400.; Sender's Comments: V0.20210457363-COVID-19 VACCINE AD26.COV2.S -Thrombosis. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>

COVID19 VACCINE	JANSEN	1276633-1	Unknown	Unknown	CLOTS; This spontaneous report received from a physician (source: news report) concerned 6 female patients. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry unknown) dose, start therapy date were not reported, frequency 1 total administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. The reporter called in regarding an event of clot experienced by 6 patients in the news on an unspecified date. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of clots was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210456400 and 20210457363.; Sender's Comments: 20210457370-covid-19 vaccine ad26.cov2.s-Blood clot. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
COVID19 VACCINE	JANSEN	1281336-1	30-39 years	Unknown	Overly tired, shortness of breath, chest pain, leg pain After 3wks of symptoms patient(self) went to hospital and it has been discovered patient has ( self) has a blood clot in Right lung. Patient (self) has no record or history of blood clots. Was treated with heparin while in hospital. Has since been discharged and sent home with a prescription for anticoagulant.
COVID19 VACCINE	JANSEN	1282231-1	65+ years	Unknown	I experienced blood clots, also had bilateral leg pain and lower back pain. I currently in the hospital.
COVID19 VACCINE	JANSEN	1284648-1	65+ years	Unknown	PULMONARY EMBOLISM; THROMBOSIS; COR PULMONALE ACUTE/ DYSPNOEA; HYPOXIA; DIZZINESS; COUGHING; This spontaneous report received from a patient via a Regulatory Authority Vaccine Adverse Event Reporting System (VAERS) (VAER reference number 1120494) concerned a 68 year old female unknown ethnicity. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805020, and expiry: UNKNOWN) dose was not reported, administered on 06-MAR-2021 14:15 for prophylactic vaccination. Concomitant medications included amitriptyline for sleep, and zolmitriptan for migraine. On 07-MAR-2021 08:30, the subject experienced pulmonary embolism, thrombosis, cor pulmonale acute/ dyspnoea, hypoxia, dizziness, coughing, and was hospitalized (date unspecified). On 12-MAR-2021, Laboratory data included: COVID-19 virus test negative (NR: not provided) Negative. Laboratory data (dates unspecified) included: Blood pressure (NR: not provided) normal, Blood test (NR: not provided) normal, CT scan (NR: not provided) Pulmonary Embolism, Chest X-ray (NR: not provided) normal, Diagnostic ultrasound (NR: not provided) No blood clots or vein thrombosis, Echocardiography (NR: not provided) Increased pressure on the right side of heart due to blood clots, and Heart rate (NR: not provided) elevated. Treatment medications (dates unspecified) included: oxygen, salbutamol, and rivaroxaban. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the pulmonary embolism, thrombosis, cor pulmonale acute/ dyspnoea, hypoxia, dizziness, coughing was not reported. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition); Sender's Comments: V2:Additional version created for MAC update. This updated information does not alter the causality of previously reported events. 20210441745-Covid-19 vaccine ad26.cov2.s-Thrombosis, pulmonary embolism, Cor pulmonale acute, Hypoxia, dizziness, cough. These events are considered unassessable. These events has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the events.

COVID19 VACCINE	JANSSEN	1284650-1	30-39 years	Unknown	<p>MIGRAINE; FEVER; HEADACHE; ARM PAIN; POTENTIAL BLOOD CLOT; This spontaneous report received from a patient concerned a 35 year old female. The patient's height, and weight were not reported. The patient's past medical history included stroke, and concurrent conditions included non-smoker, and sulfa allergy (anaphylactic). The patient experienced drug allergy when treated with nitrofurantoin. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 206A21A, expiry: UNKNOWN) dose was not reported, administered on 10-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On 10-APR-2021, patients arm was hurting and on the 11-APR-2021, night patient started having a headache. On 11-APR-2021, the patient had a fever of 103 and a migraine on 12-APR-2021. Patient took 2 Tylenol and rested in bed for the whole day. On 12-APR-2021, patient saw the physician due to her migraine. The physician was concerned that the patient may have a potential blood clot since the patient has had a stroke in 2016. Physician wanted her to get a MRV (Magnetic Resonance Venography) with contrast of the brain to make sure patient does not have another stroke and also prescribed baby aspirin until she can get the MRV The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from arm pain, fever, and headache, had not recovered from migraine, and the outcome of potential blood clot was not reported.. This report was serious (Other Medically Important Condition).; Sender's Comments: 20210443400-Covid-19 vaccine ad26.cov2.s-Potential blood clot. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: MEDICAL HISTORY</p>
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COVID19 VACCINE	JANSSEN	1284651-1	30-39 years	Unknown	<p>HEADACHE; BLURRY VISION; NECK STIFFNESS; NAUSEA; VOMITING; CEREBRAL VENOUS SINUS THROMBOSIS; DURAL VENOUS SINUS THROMBOSIS; RIGHT INTERNAL JUGULAR VEIN THROMBOSIS; INTRAPARENCHYMAL HEMORRHAGE; LOW PLATELET COUNT; This spontaneous report received from a patient via the VAERS (Vaccine Adverse Event Reporting System)(VAERS ID: 1224712) and concerned a 34-year-old white female. The patient's weight and height were not reported. The patient medical history included being 4 months post partum. The patient had no drug, food or other product allergies, and had no chronic or long-standing conditions. The patient received COVID-19 vaccine Ad26.CoV2.S (suspension for injection, route of administration and batch number not reported), dose was not reported, administered on 23-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. From an unspecified date, the patient had 2 weeks of headaches and blurry vision, 2 to 3 days of neck stiffness and nausea with 1 episode of vomiting and had been transferred to the current hospital from another. On 04-APR-2021 (12 days post-vaccination), the patient was diagnosed with dural venous sinus thrombosis (DVST), transverse/sigmoid (cerebral venous) sinus thrombus (CVST) with associated intraparenchymal hemorrhage in the right temporal lobe as well as thrombosis of the right internal jugular vein (thrombus). Magnetic resonance imaging (MRI) impressions showed there was a re-demonstrated of intraparenchymal hematoma in the right posterior temporal lobe measuring approximately 6.2 x 3.6 cm in maximal axial dimensions. There was surrounding edema and associated mass effect with effacement of the right temporal horn and right-to-left midline shift measuring 5 mm. There was medialization of the right uncus without transtentorial herniation. The basal cisterns were otherwise patent. There was dural thickening and hyperenhancement overlying the hemorrhage. There was prominent cortical veins along the right frontal temporoparietal convexity consistent with venous congestion. There was also a small are of vasogenic edema in the right anterior temporal lobe separate from the hematoma. There was a right mastoid effusion, but normal orbitals and the calvarium and skull base were unremarkable. Magnetic resonance venography (MRV) results revealed non-opacification of the torcula, right transverse sinus, right sigmoid sinus and upper internal jugular vein compatible with occlusive thrombosis. A small amount of thrombus also extended into the left transverse sinus. The superior sagittal sinus, remainder of the left transverse sinus, left sigmoid sinus, left upper internal jugular vein, straight sinus, vein of Galen and bilateral internal cerebral veins demonstrated normal contrast opacification. The patient's platelet count was 126 upon admission (normal range [NR] not provided), with other workup laboratory test results reported as pending. The action taken with COVID-19 vaccine Ad26.CoV2.S was not applicable. The outcome of the right internal jugular thrombus, intraparenchymal hemorrhage, DVST, CVST, headache, blurry vision, neck stiffness, nausea and vomiting was reported as unknown. This report was serious (caused/prolonged hospitalization and other medically important condition).; Sender's Comments: V0: This case concerns a 34-year-old white female who experienced cerebral venous sinus thrombosis (CVST), dural venous sinus thrombosis, right internal jugular vein thrombosis, and cerebral hemorrhage 12 days after receiving covid-19 vaccine ad26.cov2.s for prevention of symptomatic SARS-CoV-2 virus infection. The patient</p>
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COVID19 VACCINE	JANSSEN	1284658-1	65+ years	Unknown	<p>CLOTS IN LEG; PULMONARY EMBOLISM; FELT WEAK/WEAKNESS; WAS NOT FEELING GOOD; SPORADIC TIREDNESS; SORE ARM; This spontaneous report received from a patient concerned a 73 year old Hispanic or Latino male. The patient's height, and weight were not reported. The patient's past medical history included exposure to agent orange with vision, high pressure in eyes, glaucoma, few eye surgeries, high cholesterol, high blood sugar, and pain in knees, and concurrent conditions included non-smoker, and no alcohol use, and other pre-existing medical conditions included the patient had no known allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805018, and expiry: UNKNOWN) dose was not reported, 1 total administered on 27-MAR-2021 to left arm for prophylactic vaccination. No concomitant medications were reported. Symptoms were started after 15 days of vaccination, the patient took a trip on 01-APR-2021 and was feeling ok. The patient returned on 16-APR-2021 from trip. On 17-APR-2021, the patient experienced fast heart rate and stated that he used to be a long distance runner and he felt like running marathon again but worst. On 17-APR-2021, the patient felt weak and faint, lightheaded. On APR-2021 the patient experienced sore arm. The patient went to hospital and then his wife continued to provide information over call. On 17-APR-2021, the patient was not feeling good and heart started racing. The patient and his wife waited for one day and on 19-APR-2021 patient went to hospital for check-up. The patient had to be released from hospital by 15:00, however by 20:00 the doctor called to patient's wife and told that patient rushed to intensive care unit (ICU) because they discovered one clot that disintegrated and went to both the lungs on 19-APR-2021 as the reason for patient's slow breathing and accelerated heart rate which were occurred on 17-APR-2021. The doctor said there were many other clots still in patient's leg on 19-APR-2021. The patient was prescribed a very strong anticoagulant in hospital and at home on a different anticoagulant. The patient was on very strict regimen with no exercise. On APR-2021, the patient experienced weakness, difficulty breathing and sporadic tiredness. The patient was admitted on 19-APR-2021 for 4 days and discharged on 22-APR-2021. Laboratory data included: Electrocardiogram (EKG) (NR: not provided) Blood clots in both lungs and leg and lots of other test performed at hospital which were unknown. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from pulmonary embolism, and the outcome of sore arm, felt weak/weakness, was not feeling good and sporadic tiredness was not reported. This report was serious (Hospitalization Caused / Prolonged, Other Medically Important Condition, and Life Threatening).; Sender's Comments: V0 -Covid-19 vaccine ad26.cov2.s-1) Pulmonary embolism. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). 2)-Clots in legs. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>
COVID19 VACCINE	JANSSEN	1284660-1	Unknown	Unknown	<p>CLOTS; This spontaneous report received from a physician concerned a patient of unspecified age and sex. The patient's weight, height and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: Unknown) frequency one total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient died due to clot. It was unknown if autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died to clots on an unspecified date. This report was serious (Death). This case, from the same reporter is linked to 20210457363.; Sender's Comments: V0: 20210456400-Covid-19 vaccine ad26.cov2.s-Death. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: CLOTS</p>

COVID19 VACCINE	JANSSEN	1284680-1	Unknown	Unknown	SIDE EFFECTS INVOLVING SANGUINEOUS CLOTS; This spontaneous report received from a consumer (source: article published) concerned 6 patients. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry: unknown) dose, start therapy date were not reported, frequency 1 total administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. It was reported that the center for disease control and prevention (CDC) and arm of food and drug administration (FDA), the agency responsible for health surveillance, was about to discuss whether the pause in the use of covid-19 vaccine ad26.cov2.s is expected to continue after 6 people developed rare side effects involving sanguineous clots on an unspecified date. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of side effects involving sanguineous clots was not reported. This report was serious (Other Medically Important Condition); Sender's Comments: V0-20210460381-covid-19 vaccine ad26.cov2.s-side effects involving sanguineous clots. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
COVID19 VACCINE	JANSSEN	1285459-1	40-49 years	Unknown	BLOOD CLOTS
COVID19 VACCINE	JANSSEN	1287916-1	Unknown	Unknown	ESCALATING PAIN IN LOWER BACK; ESCALATING PAIN IN LEG; BLOOD CLOT IN LEG; VACCINE-INDUCED IMMUNE THROMBOTIC THROMBOCYTOPENIA; This spontaneous report received from a patient via a company representative (media article) concerned a 4 decade old male (man in 30s). The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, frequency once total, administered on 08-APR-2021 for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date in APR-2021, within two weeks after receiving a dose of the J&J COVID-19 Vaccine, the patient experienced blood clot in leg. Patient began to experience escalating pain in the lower back and leg on 16-APR-2021. Patient was hospitalized on 21-APR-2021 with escalating pain in his lower back and leg, 13 days after taking the vaccine. It was reported that this was the first male patient with VITT (vaccine-induced immune thrombotic thrombocytopenia) syndrome. The patient was recuperating and making good progress and would be discharged within a few days. Patient's bloodwork showed signature low levels of platelets and fibrinogen, a blood-clotting factor made in the liver, which had been seen in other patients with vaccine-induced clots. Bloodwork showed the patient had the same syndrome as the other patients although initial imaging did not show a blood clot. Physicians later discovered a tiny clot. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from escalating pain in lower back, escalating pain in leg, blood clot in leg, and vaccine-induced immune thrombotic thrombocytopenia. This report was serious (Hospitalization Caused / Prolonged, and Other Medically Important Condition). This case, from the same reporter is linked to 20210451418. Initial information was processed with additional information received on 28-APR-2021.; Sender's Comments: V0: This spontaneous report received from a media article concerned a man in 30s who experienced vaccine-induced thrombotic thrombocytopenia 13 days after vaccine. Medical history and concomitant medications were not reported. Eight days after vaccine, patient began to experience escalating pain in the lower back and leg. Initial imaging did not show a blood clot but physicians later discovered a ""tiny clot"" in the leg. Thirteen days after vaccine, patient was hospitalized with escalating pain in his lower back and leg. The patient was recuperating and making good progress and would be discharged within a few days. Patient's bloodwork showed ""signature low levels of platelets and fibrinogen."" Although the other risk factors (not reported) may have contributed, based on evolving knowledge of Thrombosis with Thrombocytopenia Syndrome (TTS, per definition from Brighton Collaboration - BC) and considering the low platelet count and temporal relationship to vaccination (BC Criteria level 1), the s events are assessed to have a plausible relationship with vaccination. Reporter contact information was not provided which precludes meaningful additional information in this version.""



COVID19 VACCINE	JANSSEN	1288528-1	Unknown	Unknown	<p>DEEP VEIN THROMBOSIS IN LEGS; This spontaneous report received from a patient concerned a female patient of unspecified age. The patient's height, and weight were not reported. The patient's concomitant medical conditions included non smoker. The patient is a Zumba teacher. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 041821A expiry: UNKNOWN) dose was not reported, administered on 08-APR-2021 for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, reported as several days after vaccination, the patient felt some discomfort in the leg. The patient took Tylenol and rested for two weeks, however it did not improve. The patient went to the doctor for a follow up and physical and the doctor ordered a doppler, which showed blood clots in both legs. The doctor immediately placed the patient on Eliquis 5mg. Patient reported that she needs to see a cardiologist and hematologist because she now has a DVT (deep vein thrombosis). The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the DVT was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: VO:20210505469-Covid-19 vaccine ad26.cov2.s-Deep vein thrombosis. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p>
COVID19 VACCINE	JANSSEN	1288631-1	50-59 years	Unknown	<p>BLOOD CLOT IN LEFT LEG; DIFFICULTY SLEEPING; SOME LEG CRAMPS; SWELLING; This spontaneous report received from a patient concerned a 55 year old male. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry date: unknown) dose, 1 total on an unknown date in APR-2021 (reported as about three weeks ago from the date of reporting) on left arm for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. Since an unknown date in APR-2021 (reported as about a week ago), the patient experienced swelling and some leg cramps. It was reported that nothing (swelling and leg cramps) was dramatic initially, however, they worsened. On 28-APR-2021 (reported as last night), the patient had difficulty in sleeping. On 29-APR-2021, the patient was diagnosed with blood clot in left leg by his doctor. At the time of report (reported as currently), the patient was in transport to a hospital for further evaluation. The patient further mentioned that he did not have possession of the vaccination card, but his wife had it and she would be arriving at hospital later. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clot in left leg, swelling, and some leg cramps, and the outcome of difficulty sleeping was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: VO: -COVID-19 VACCINE AD26.COVID.S-Blood Clot in leg. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p>

COVID19 VACCINE	JANSSEN	1288634-1	40-49 years	Unknown	<p>DIZZINESS; SHORTNESS OF BREATH; PULMONARY EMBOLISM; This spontaneous report received from a physician concerned a 48 year old male. The patients weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total administered on 12-MAR-2021 for prophylactic vaccination. Vaccination site was not reported. The batch number was not reported and has been requested. No concomitant medications were reported. On APR-2021, the patient experienced pulmonary embolism. Laboratory data included: Computerized tomogram thorax (NR: not provided) positive, Ear, nose and throat examination (NR: not provided) negative and Platelet count (NR: not provided) 197. On 04-APR-2021, the patient experienced dizziness and shortness of breath. Full neuro, cardiac, Ear, nose and throat workup and evaluation was negative in Erectile dysfunction and follow up clinics. Patient had a Wells Criteria of zero, and was hemodynamically stable, platelet was 197. Patient started with DDIMER which was 560 and later chest Computerized tomogram thorax was positive for right lower lobe Pulmonary embolus. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the dizziness, shortness of breath and pulmonary embolism was not reported. This report was serious (Other Medically Important Condition). Sender's Comments: V0: -Covid-19 vaccine ad26.cov2.s-Pulmonary embolism. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).</p>
COVID19 VACCINE	JANSSEN	1288635-1	Unknown	Unknown	<p>BLOOD CLOTS; This spontaneous report received from a consumer via social media through a company representative and concern a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, expiry date: Unknown) dose, 1 total dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient experienced blood clots. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clots was not reported. This report was serious (Other Medically Important Condition); Sender's Comments: V0- Covid-19 vaccine ad26.cov2.s-blood clots.This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p>

COVID19 VACCINE	JANSEN	1288636-1	60-64 years	Unknown	<p>CEREBRAL VENOUS THROMBOSIS; VISUAL IMPAIRMENT; HYPOAESTHESIA/ NUMBNESS IN ARM; This spontaneous report was received from a health care professional via a Regulatory Authority Vaccine Adverse event Reporting system (VAERS) (VAER reference number 1207958) and concerned a 64 year old male of unspecified race and ethnicity. The patient's height and weight were not reported. The patient's concurrent conditions included pollen allergy. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805029 expiry: UNKNOWN) dose was not reported. 1 total, administered on 16-MAR-2021 for prophylactic vaccination on left arm. Concomitant medications included atorvastatin and lisinopril; both for unknown indication. On 07-APR-2021, the patient experienced cerebral venous thrombosis, hypoaesthesia, and visual impairment. The patient had cerebrovascular thrombus with partial loss of sight and numbness of his left arm. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from cerebral venous thrombosis, hypoaesthesia, visual impairment. This report was serious (Disability Or Permanent Damage). This case version (1) was created on 30-APR-2021 for the purpose of quality improvement the following corrections were made. The MAC was added for the pharmacovigilance narrative.; Sender's Comments: V1: This spontaneous report was received from a health care professional via VAERS (ID: 1207958) and concerned a 64-year-old male of unspecified race and ethnicity who experienced cerebral venous sinus thrombosis (CVST) 22 days after vaccine. Concurrent conditions included pollen allergy and concomitant medications included atorvastatin and lisinopril. Twenty-two days after vaccine, the patient experienced CVST, hypoaesthesia, and visual impairment. The patient had cerebrovascular thrombus with partial loss of sight and numbness of his left arm. Specific imaging and laboratory results, including platelet count, were not reported. Information is limited in this case, and the occurrence of CVST could represent background incidence of such events in the general population. The platelet count is not reported and thus this case does not meet the Brighton Collaboration (BC) definition for Thrombocytopenia Thrombosis Syndrome (TTS) with BC Level 5 (not a case of TTS.)</p>
COVID19 VACCINE	JANSEN	1291581-1	Unknown	Unknown	<p>POSSIBLE CLOT IN THE LEFT ARM; PAIN IN THE LEFT ARM/SIDE; This spontaneous report received from a patient via a company representative concerned a 6 decade old female. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient experienced possible clot in the left arm, and pain in the left arm/side, and was hospitalized (date unspecified). it was reported that the patient had reaction to the JnJ vaccine. She was being watched closely and taken care of. Pain on the left arm/side. They think it as clot in the left arm. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the pain in the left arm/side and possible clot in the left arm was not reported. This report was serious (Hospitalization Caused / Prolonged).; Sender's Comments: v0;20210456346-Covid vaccine ad26.cov2.s-Possible clot in the left arm. Follow-up received regarding Clinical Details. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). v0;20210456346-Covid vaccine ad26.cov2.s-Pain in left arm. Follow-up received regarding Clinical Details. This event(s) is labeled per RSI and is therefore considered potentially related.</p>

COVID19 VACCINE	JANSSEN	1291587-1	Unknown	Unknown	<p>BLOOD CLOT; This spontaneous report received from a consumer via social media through a company representative and concerned a patient of unspecified age and sex The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unk) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient experienced blood clot three weeks later without any underlying conditions. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of blood clot was not reported. This report was serious (Other Medically Important Condition). This case, from the same reporter is linked to 20210504574.; Sender's Comments: V0:20210503763-Covid-19 vaccine ad26.cov2.s-Blood clot. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.</p>
COVID19 VACCINE	JANSSEN	1293992-1	Unknown	Unknown	<p>THROMBOCYTOPENIA; LEFT LEG DVT; RIGHT TRANSVERSE SINUS; INTERNAL JUGULAR VEIN THROMBOSIS; SIGMOID SINUSES; SWELLING OF LOWER EXTREMITIES; LEFT LOWER EXTREMITY PAIN; SHOULDER PAIN; NECK SPRAIN; MUSCLE SPASM; RIGHT SIDE NECK PAIN; SHORTNESS OF BREATH; CHILLS; INTERMITTENT HEADACHE; MYALGIA; This spontaneous report was originally received from the patient via the United States Regulatory Authority Food and Drug Administration (FDA) Vaccine Adverse Event Reporting System (VAERS), case reference number 1218651and concerned a White, not Hispanic or Latino 37-year-old female. The patient's weight and height were not reported. The patient's concurrent conditions included migraine headaches and 7 months post-partum. The patient did not have known allergies. The patient's BMI was 24 with no history of smoking or cancer. The patient did not have these previous events prior. The patient was not pregnant. It is unknown as to history of autoimmune disease, genetic or acquired risk factors or previous clotting disorders. The patient received COVID-19 vaccine Ad26.CoV2.S (suspension for injection, intramuscular, batch number 1808609) dose not reported, administered once on 23-MAR-2021 at 14:30 into left arm for prophylactic vaccination. No concomitant medications were reported. On 24-MAR-2021, the patient developed myalgias, headache, shortness of breath, and chills which resolved in 24 hours. On 02-APR-2021, the patient developed headache intermittent from right to left side of head for which patient was seen at an urgent care. The patient was prescribed butalbital/acetaminophen/caffeine (Fioricet). On 05-APR-2021, the patient developed right-sided neck pain. On 06-APR-2021, the patient was tested for COVID-19 virus test and was negative. On 08-APR-2021, the patient experienced neck sprain, muscle spasm and shoulder pain. The patient was seen in the emergency department (ED) for headache and head and shoulder. The patient took ibuprofen. Platelets were 90,000/mcl. Computed tomography (CT) scan of the head without contrast was unremarkable. The patient was diagnosed with headache and neck sprain and was prescribed ibuprofen 600 mg, take 1 tablet by mouth every 8 hours, and diazepam 5 mg, take 1 tablet by mouth 3 times a day as needed for muscle spasm. On 12-APR-2021, the patient experienced left lower extremity (LLE) pain. The left foot was weak and pressure could not be put upon it. On 14-APR-2021, the patient followed up with neurologist outpatient as directed by the emergency department provider and was advised to get an magnetic resonance venography (MRV) and left lower extremity Doppler. The patient was prescribed tramadol 50 mg and butalbital/acetaminophen/caffeine by the neurologist. On 15-APR-2021, the patient presented with headache, neck pain and left leg pain. Platelet count was 122,000.The patient experienced thrombocytopenia, right transverse sinus, sigmoid sinuses vein and internal jugular thrombosis. The patient went to the ED before outpatient magnetic resonance venography (MRV) and LLE Doppler could be done due to worsening right-sided neck pain and inability to ambulate comfortably due to lower extremity pain that had been worsening over several days. Upon examination, there was subtle swelling to left lower extremity and Doppler revealed multiple deep vein thrombosis (DVT) in left lower extremity. CT head without contrast was unremarkable, however, CT venogram of the brain revealed thrombi of the right transverse sinus and sigmoid sinuses, as well as internal jugular vein thrombosis (IJ). The patient was initiated on argatroban and</p>

COVID19 VACCINE	JANSSEN	1294816-1	Unknown	Unknown	BLOOD CLOTS; UNABLE TO WALK/TEMPORARY DISABLED; This spontaneous report received from a source from a consumer via a company representative concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: Unknown) frequency one total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. The consumer reported that the patient on an unspecified date experienced blood clots and was unable to walk. The patient was under doctor care and was temporary disabled. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient had not recovered from blood clots, and unable to walk/temporary disabled. This report was serious (Other Medically Important Condition, and Disability Or Permanent Damage).; Sender's Comments: 20210502999-covid-19 vaccine ad26.cov2.s-Blood clots, unable to walk. This event(s) is considered un-assessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
COVID19 VACCINE	MODERNA	0988302-1	40-49 years	Unknown	Very heavy period. Passed multiple golf ball sized clots for several hours.
COVID19 VACCINE	MODERNA	0994450-1	Unknown	Unknown	Pulmonary embolism; Chest pain; Shortness of breath; Arm swelling; Soreness in her arm; Local reaction in the lymph nodes of the axilla; A spontaneous report was received from a physician concerning a female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed pulmonary embolism, arm swelling and soreness, shortness of breath, chest pain and a reaction in the lymph nodes of the axilla. The patient's medical history includes pulmonary embolisms. Relevant concomitant medications were not reported. On an unknown date, approximately five days prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. The patient experienced a pulmonary embolism, arm swelling, arm soreness, a local reaction in the lymph nodes of the axilla, shortness of breath, and chest pain. CT scan showed small acute embolism. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events pulmonary embolism, arm swelling and soreness, shortness of breath, chest pain and a reaction in the lymph nodes of the axilla were not reported.; Reporter's Comments: Company Comment: This spontaneous report concerning a female patient who experienced unexpected serious event of pulmonary embolism and nonspecific events of arm swelling and soreness, a reaction in the lymph nodes of the axilla, shortness of breath, and chest pain. The patient developed the events on an approximately 5 days after the first dose of the mRNA-1273 vaccine (Lot #: unknown, expiration date-unknown). Pulmonary embolism was confirmed via CT. There is not enough information to adequately evaluate and assess the event of pulmonary embolism. Swelling and soreness, a reaction in the lymph nodes of the axilla are temporally associated with the vaccine administration and in the absence of any other etiology, a causal association between these events and the administration of mRNA-1273 vaccine cannot be excluded. main field defaults to 'possibly related' for all events.
COVID19 VACCINE	MODERNA	1049773-1	50-59 years	Unknown	Patient died on 02/20/2021. Cause of death was pulmonary embolism.
COVID19 VACCINE	MODERNA	1074304-1	Unknown	Unknown	PE; DVT; A spontaneous report was received from a pharmacist concerning patient (age and gender unknown) who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced a pulmonary embolism (PE) and deep vein thrombosis (DVT). The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On an unknown date, the patient received the first of two planned doses of mRNA-1273 (Batch number not provided) intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, the patient experienced a PE and DVT. Treatment information was not provided. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the events, PE and DVT, were not reported.; Reporter's Comments: Very limited information regarding the reported events have been provided at this time. No additional information is expected as consent to follow up was denied.
COVID19 VACCINE	MODERNA	1108470-1	65+ years	Unknown	Pulmonary Embolism Narrative: Patient was hospitalized with acute pulmonary embolism on 2/12/2021. Was started on Eloquis and discharged on 2/15/2021, with primary diagnosis of acute PE and BLE DVT. Secondary diagnosis of acute systolic heart failure with bilateral pleural effusions. On 2/17 we got notification that patient was placed on hospital.

COVID19 VACCINE	MODERNA	1115043-1	65+ years	Unknown	<p>Blood Clot in Leg; Tenderness; A spontaneous report was received from a consumer concerning a 68-year-old, male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced blood clot in leg and tenderness. The patient's medical history was not provided by the reporter. Concomitant medications reported included diltiazem hydrochloride, atorvastatin calcium and acetyl salicylic acid. On 13-Feb-2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number:031M2QA) through intramuscularly in the right arm for prophylaxis of COVID-19 infection. On 13-Feb-2021, following administration of the vaccine, the patient had tenderness in his leg that continued until he sought out medical treatment. After medical treatment it was concluded that the patient has a blood clot in his leg and has to receive medical treatment to resolve that condition. The treatment information included rivaroxaban. Action taken with mRNA-1273 in response to the events was not applicable. The events, blood clot in leg and tenderness were considered recovered.; Reporter's Comments: There is not enough information to assess the causal association between the reported event of blood clot in leg and the administration of the mRNA-1273 vaccine. Critical details such as the patient's medical history is lacking. Additional information has been requested. However, based on temporal association between product administration and the event of tenderness, a causal relationship cannot be excluded.</p>
COVID19 VACCINE	MODERNA	1131197-1	65+ years	Unknown	<p>blood clot in his left leg; A spontaneous report was received from a consumer concerning a 70-year-old, male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and developed a blood clot in his left leg/thrombosis. The patient's medical history was not provided. No relevant concomitant medications were provided. On 10 Feb 2021, approximately two weeks prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 030M20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. Two weeks after the vaccination, the patient developed a blood clot in his left leg. He got his second vaccine on 10 Mar 2021. Treatment information was not provided. There was no change planned to the dosing schedule of mRNA-1273 in response to the event. The outcome of the event blood clot in his left leg was not reported.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the event, a causal relationship cannot be excluded.</p>
COVID19 VACCINE	MODERNA	1133011-1	50-59 years	Unknown	<p>Diagnosed with DVT; Leg got really swollen/swelling of the lower calf area; Sore arm; Sore arm; Pulled a muscle; A spontaneous report was received from a consumer concerning a 57-year-old male patient, who received Moderna's COVID-19 vaccine (mRNA -1273) and experienced events, DVT/ deep vein thrombosis, pulled a muscle/myalgia, swelling of the lower calf area(leg got really swollen)/peripheral swelling and calf pain(sore arm)/pain in extremity. The patient's medical history was not provided. No relevant concomitant medications were reported. On 12 Jan 2021, prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number: unknown) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 09 FEB 2021, prior to the onset of the symptoms, the patient received their second of two planned doses of mRNA-1273 (Batch number: 013M20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. On 12 Jan 2021, after receiving the vaccine the patient had sore arm. On an unspecified date in Jan 2021, the patient had experienced a pull in his muscle in his calf and lower calf area got swollen. On 09 Feb 2021, after receiving the second dose of vaccine he had experienced a sore arm. On 11 Mar 2021, his leg got really swollen and on 12 Mar 2021, he visited hospital where it got diagnosed as DVT in his right lower calf. Treatment for the events included blood thinner Apixaban. Patient is concerned about possibility of indirect relation of events to the vaccine. The patient received both scheduled doses of mRNA-1273 prior to the events, therefore action taken with the drug in response to the events is not applicable. The outcome of the event DVT, leg got really swollen, swelling of the lower calf area and calf pain were unknown at the time of this report. The event pulled a muscle is not resolved. The event sore arm which the patient experienced for both the doses got resolved on 13 Jan and 14 Jan 2021, respectively.; Reporter's Comments: Based on the information provided which includes a strong temporal association a causal association between the event of sore arm and the administration of mRNA-1273 cannot be excluded. The events of DVT, pulled muscle and swelling of lower calf is assessed as unlikely related to mRNA-1273. Events were all attributed to muscle strain.</p>

COVID19 VACCINE	MODERNA	1135306-1	65+ years	Unknown	Clot on the lower left leg; foot and ankle swollen; A spontaneous report was received from a physician concerning a 72-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced foot and ankle swelling (joint swelling) and clot on the lower left leg (deep vein thrombosis). The patient's medical history was not provided. No relevant concomitant medications were reported. No information on allergies were provided. The reported stated that the patient was physically and mentally healthy before vaccination. On 5 Feb 2021 , prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 012M20A) via intramuscular route on left side for prophylaxis of COVID-19 infection. On 5 Mar 2021 prior to the onset of the events, the patient received their second planned dose of mRNA-1273 (Lot number: 036A21A ) via intramuscular route on left side for prophylaxis of COVID-19 infection. Doctor found a clot in her lower left leg. Patient said that on Feb 2 before receiving the first dose on Feb 5 needed to have an x ray and blood work due to foot and ankle got swollen. Patient said they checked it for different things and that the doctor thought it would be a pseudo gout. As the ankle was still swollen patient went to her family doctor and doctor insisted to have a test for deep vein thrombosis. They have found a clot on the lower left leg. The patient had stated she have not a had a surgery or an injury and that it happened between doses. Treatment drug used for the event included was apixaban. Action taken with mRNA-1273 in response to the events was not applicable. The outcome for the events, foot and ankle swelling and clot on the lower left leg, was considered unknown.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested. It was reported that the patient had an x ray and blood work due to foot and ankle swelling before receiving the first dose of vaccine and that the doctor thought it to be a pseudo gout.
COVID19 VACCINE	MODERNA	1135458-1	65+ years	Unknown	Severe pancreatitis with no specific cause identified followed by complications of peritonitis, fluid in lungs of 80%, deep leg vein thrombosis, and multiple episodes of coronary arrest and systemic inflammation.
COVID19 VACCINE	MODERNA	1135707-1	Unknown	Unknown	Blacked out; Multiple blood clots; inflammation in spine; A spontaneous report was received from a consumer, concerning a female patient of unspecified age, who received Moderna's COVID-19 vaccine and experienced multiple blood clots/ thrombosis, inflammation in spine/inflammation, blacked out/loss of consciousness. The patient's medical history included blood clots. Concomitant product use was not provided by the reporter. On an unspecified date, prior to the onset of events, the patient received their first of two planned doses of mRNA-1273 via unknown route for COVID-19 infection prophylaxis. On 11 Mar 2021, the reporter stated that her sister received the Moderna vaccine and she had multiple blood clots, inflammation in spine and blacked out. The events multiple blood clots and blacked out were assessed as serious based on IME list. Treatment information was not reported. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events multiple blood clots, inflammation in spine and blacked out was reported to be unknown at the time of this report.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1135716-1	Unknown	Unknown	Blood clot in lungs; Pneumonia; A spontaneous report was received from a consumer concerning her husband, male patient who developed blood clot in lungs/pulmonary embolism, pneumonia/pneumonia. The patient's medical history included Parkinson's. Concomitant product use was not provided by the reporter. The patient received their first of two planned doses of mRNA-1273 for prophylaxis of COVID-19 infection. On 4 Mar 2021 the patient was admitted due to blood clot in lungs and pneumonia. The medically significant event caused hospitalization. Treatment of the event included blood thinners. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events blood clot in lungs and pneumonia was not reported.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

COVID19 VACCINE	MODERNA	1135720-1	60-64 years	Unknown	<p>blood clots in upper thigh down to foot; swelling of the foot; tingling; clot was burning and hot; A spontaneous report was received from a consumer concerning a 62-years-old patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events blood clots in upper thigh down to foot, swelling of the foot, tingling, and clot was burning and hot. The patient's medical history included insertion of a blood clot filter. Concomitant medications reported were Xarelto for drug use for unknown indication. She is also taking 17 other medications (not provided) and has other medical issues (not provided). She also has a blood clot filter inside her body (location not provided). She also wears compression and diabetic socks. On 25 Feb 2021, prior to the onset of the events the patient received the first of two planned doses of mRNA-1273 (lot/batch: L014M20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On an unknown date, the patient experienced the event(s) blood clots in upper thigh down to foot, swelling of the foot, tingling, clot was burning and hot. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of event(s), blood clots in upper thigh down to foot, swelling of the foot, tingling, clot was burning and hot was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p>
COVID19 VACCINE	MODERNA	1137224-1	65+ years	Unknown	<p>Develop a blood clot on their left knee; Left leg kept swelling up; A spontaneous report was received from a physician concerning a 83-year-old, female patient, who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced a blood clot on her left knee and left leg kept swelling up. The patient's medical history included cholesterol unspecified. Products known to have been used by the patient, within two weeks prior to the event, included vitamin D and medications for cholesterol. On 26 Feb 2021, prior to the onset of the symptoms, the patient received her first of two planned doses of mRNA-1273 (Batch number: 038K20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On an unspecified date after the vaccination patient developed blood clot on left leg, leg also kept swelling. Relevant treatment for the event included blood thinners and aspirin. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events, blood clot on their left knee and left leg kept swelling up, was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>
COVID19 VACCINE	MODERNA	1143465-1	65+ years	Unknown	<p>Superficial blood clot in the leg/area is sore to touch; A spontaneous report was received from a consumer (patient), concerning a 82-years-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced superficial blood clot in the leg/area is sore to touch (thrombosis). No medical history was reported. No concomitant medications were reported. On 19 Jan 2021, the patient received the first of two planned doses of mRNA-1273 (Lot number: not provided), on 15 Feb 2021, the patient received the second of two planned doses of mRNA-1273 (Lot number: 027L20A) intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, the patient experienced a superficial blood clot in her leg (medically significant). She also reported that the area was sore to touch. The doctor prescribed medication to treat her problem, but they said to wait a week to see if it solved on its own before taking it. She was also applying ice pack on the affected area. No further information as reported. The patient received both scheduled doses of mRNA-1273 prior to the event, therefore action taken with the drug in response to the event is not applicable. The event of superficial blood clot in the leg/area is sore to touch (thrombosis) was unresolved. The reporter did not provide assessment for the event of superficial blood clot in the leg/area is sore to touch (thrombosis).; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.</p>

COVID19 VACCINE	MODERNA	1148725-1	Unknown	Unknown	<p>blood clot in her leg/clots in upper thigh on inside of thigh which were very sore; more lumps in crease of leg/knee/lump red and raised/ones behind the knee in the crease are still there and hard as a rock; lump was red and raised; Patient reports it was really sore up toward groin; A spontaneous report was received from a consumer concerning herself, who is 68-years old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced thrombosis, mass excision, groin pain, skin swelling, developed more clots in upper thigh on inside of thigh which were very sore. No medical history was reported. No concomitant medications were reported. On 04-Feb-2021, the patient received their first of first planned doses of mRNA-1273 (Lot number: 031120A) was administered intramuscularly with unknown site for prophylaxis of COVID-19 infection. On an unknown date, an unspecified amount of time, the patient developed a blood clot in her leg, her lump was red and raised. She went to the doctor and they told her to put a warm compress and keep her leg up. The lumps did not start to go down. She started to develop more lumps in crease of leg/knee. Patient went to vascular doctor who did an ultrasound and diagnosed superficial thrombophlebitis. Patient then went to get second Moderna vaccine on 10MAR2021 (lot#036021A). She developed more clots in upper thigh on inside of thigh which were very sore. Patient reports it was really sore up toward groin. She went to doctor again and they put her on Xarelto, and Aleve as directed on box. Symptoms are ongoing. Original lumps were no longer sore to the touch, ones behind the knee in the crease are still hard as a rock. New lumps after second dose are tender. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of the events were not recovered. The reporter did not provide an assessment for the events; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>
COVID19 VACCINE	MODERNA	1153133-1	Unknown	Unknown	<p>Blood clot; Swelling in lower leg; A spontaneous report was received from a consumer concerning a male patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced swelling in lower leg and blood clot. The patient's medical history was not provided. Concomitant medications reported included blood thinners Xarelto. On 21 Feb 2021 prior to the onset of the events, the patient received his first of two planned doses of mRNA-1273 (Lot number: unknown) for prophylaxis of COVID-19 infection. Treatment for the events was unknown. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, swelling in lower leg and blood clot was unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>
COVID19 VACCINE	MODERNA	1188842-1	65+ years	Unknown	<p>Blood clot; Fatigue extreme; muscle soreness; loss of appetite; Unable to get out of bed for four days so then they took her to the ER; Lack of circulation on legs due to blood clot produced a wound to develop in her leg; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clot) and FATIGUE (Fatigue extreme) in a 74-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 025A21A and 007M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. On 28-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (Blood clot) (seriousness criteria hospitalization and medically significant), FATIGUE (Fatigue extreme) (seriousness criterion hospitalization), MYALGIA (muscle soreness), DECREASED APPETITE (loss of appetite), MOBILITY DECREASED (Unable to get out of bed for four days so then they took her to the ER) and LIMB INJURY (Lack of circulation on legs due to blood clot produced a wound to develop in her leg). The patient was hospitalized on 22-Mar-2021 due to FATIGUE and THROMBOSIS. At the time of the report, THROMBOSIS (Blood clot), FATIGUE (Fatigue extreme), MYALGIA (muscle soreness), DECREASED APPETITE (loss of appetite), MOBILITY DECREASED (Unable to get out of bed for four days so then they took her to the ER) and LIMB INJURY (Lack of circulation on legs due to blood clot produced a wound to develop in her leg) had not resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown Route), the reporter did not provide any causality assessments.</p>

COVID19 VACCINE	MODERNA	1189629-1	Unknown	Unknown	Blood clot on her eye after vaccination; Her HCP told her that she could wait even 3 months to get the 2nd dose; This spontaneous case was reported by a patient (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (Blood clot on her eye after vaccination) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Enucleation of eyeball. In March 2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (Blood clot on her eye after vaccination) (seriousness criterion hospitalization) and OFF LABEL USE (Her HCP told her that she could wait even 3 months to get the 2nd dose). At the time of the report, THROMBOSIS (Blood clot on her eye after vaccination) and OFF LABEL USE (Her HCP told her that she could wait even 3 months to get the 2nd dose) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Concomitant product use was unknown. Treatment information not provided. Her HCP told her that she could wait even 3 months to get the 2nd dose Patient decided not to give more information as she believed it wouldn't help her. Reporter did not allow further contact; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1194118-1	Unknown	Unknown	Blood clots; Felt extremely ill; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clots) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Cancer and Autoimmune disorder. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (Blood clots) (seriousness criterion medically significant) and MALAISE (Felt extremely ill). At the time of the report, THROMBOSIS (Blood clots) and MALAISE (Felt extremely ill) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1197857-1	Unknown	Unknown	PATIENT BEGAN SLURRED SPEECH AND WEAKNESS IN LEFT SIDE ONE WEEK AFTER VACCINATION. DAUGHTER, WHO IS A NURSE, NOTICED AND MADE PATIENT GO TO ER. THERE, PATIENT HAD A SCAN DONE THAT REVEALED TWO BLOOD CLOTS, WHICH HAD CAUSED A STROKE, IN THE BACK OF THE BRAIN. PATIENT WAS KEPT FOR OBSERVATION OVER NIGHT IN THE HOSPITAL AND THEN RELEASED.
COVID19 VACCINE	MODERNA	1202196-1	65+ years	Unknown	LOWER LIMB EMBOLISM-BLOOD CLOT, TIGHTNESS, HEAT AND PAIN WHEN WALKING, TREATING PHYSICIAN COULD NOT CONTRIBUTE TO ANY OTHER HEALTH CONDITIONS OR REASONS
COVID19 VACCINE	MODERNA	1203183-1	Unknown	Unknown	Multiple subsegmental pulmonary emboli with no history of DVT/PE. No other risk factors other than tobacco use and recent cataract surgery (<1 hour). PE occurred 9 days after last vaccine. Pt presented with chest pain and SOB.

COVID19 VACCINE	MODERNA	1204782-1	60-64 years	Unknown	Blood clot; COVID-19; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clot) in a 62-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history reported.). Concomitant products included PARACETAMOL (TYLENOL) for an unknown indication. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (Blood clot) (seriousness criterion medically significant) and COVID-19 (COVID-19). At the time of the report, THROMBOSIS (Blood clot) and COVID-19 (COVID-19) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, SARS-CoV-2 test: positive (Positive) positive. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Products known to have been used by the patient, within two weeks prior to the event, included blood thinner medication. Treatment information was not provided. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1206902-1	65+ years	Unknown	her left leg was swollen; two red clots on left leg; right feet was hurting; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (two red clots on left leg) in a 65-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. Unknown) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. On 03-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced PERIPHERAL SWELLING (her left leg was swollen), THROMBOSIS (two red clots on left leg) (seriousness criterion medically significant) and PAIN IN EXTREMITY (right feet was hurting). At the time of the report, PERIPHERAL SWELLING (her left leg was swollen), THROMBOSIS (two red clots on left leg) and PAIN IN EXTREMITY (right feet was hurting) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Further information has been requested.
COVID19 VACCINE	MODERNA	1208015-1	50-59 years	Unknown	DVT in right leg with multiple PE?s bilaterally. Treatment: oral Xarelto
COVID19 VACCINE	MODERNA	1219828-1	65+ years	Unknown	Patient received his first Moderna vaccine 3-19-21. He was due for his 2nd dose 4-16-21. We followed up with his sister due to missed appointment and was informed that he passed away 4-15-21 due to a blood clot.
COVID19 VACCINE	MODERNA	1220922-1	Unknown	Unknown	Blood clot; Pain; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clot) in a 30-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event. On 11-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (Blood clot) (seriousness criterion medically significant) and PAIN (Pain). At the time of the report, THROMBOSIS (Blood clot) and PAIN (Pain) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Company comment: Limited information regarding the events has been provided at this time and a causal relationship cannot be excluded

COVID19 VACCINE	MODERNA	1220930-1	65+ years	Unknown	<p>SHORTNESS OF BREATH; multiple pulmonary embolism; NAUSEA; MIGRAINE; low grade fever / 100 degree Fahrenheit; MYALGIA; This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 06-Apr-2021 and was forwarded to Moderna on 06-Apr-2021. This spontaneous case was reported by a pharmacist (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (multiple pulmonary embolism) and DYSPNOEA (SHORTNESS OF BREATH) in a 67-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Drug allergy (allergy to Nonsteroidal anti-inflammatory drug and Salsalate.Fluconazole) since an unknown date, Hives since an unknown date, Rash (patient develops rash with Zipro.) since an unknown date, Hypertension since an unknown date, Hypercholesterolemia since an unknown date, Prostate cancer since an unknown date and Chronic back pain since an unknown date. On 26-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 24-Mar-2021, the patient experienced PULMONARY EMBOLISM (multiple pulmonary embolism) (seriousness criteria hospitalization and medically significant). On 27-Mar-2021, the patient experienced PYREXIA (low grade fever / 100 degree Fahrenheit ) and MYALGIA (MYALGIA). On 28-Mar-2021, the patient experienced MIGRAINE (MIGRAINE) and NAUSEA (NAUSEA). On 29-Mar-2021, the patient experienced DYSPNOEA (SHORTNESS OF BREATH) (seriousness criterion hospitalization). At the time of the report, PULMONARY EMBOLISM (multiple pulmonary embolism), DYSPNOEA (SHORTNESS OF BREATH), MIGRAINE (MIGRAINE), PYREXIA (low grade fever / 100 degree Fahrenheit ), MYALGIA (MYALGIA) and NAUSEA (NAUSEA) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Computerised tomogram: for pulmonary embolism in lungs. On an unknown date, Ultrasound Doppler: Negative. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown Route), the reporter did not provide any causality assessments. Treatment included were Sumatriptan, Prednisone and home nebulize albuterol. Action taken with mRNA-1273 in response to the event was not applicable. There was complete workup done and he was diagnosed with pulmonary embolism with CAT scan with dye, multiple pulmonary embolism in the lungs, Ultrasound in legs which was negative. He reports that his D-dimer were very high. In conclusion his imaging and D-dimer pointed towards the pulmonary embolism diagnosis. Company comment: Based on the current available information and temporal association between the use of the product and the start dates of the events, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-068247 (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start dates of the events, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-068247:Same reporter/Different patient</p>
COVID19 VACCINE	MODERNA	1220993-1	Unknown	Unknown	<p>Pulmonary embolism; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Pulmonary embolism) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. Unknown) for COVID-19 vaccination. Concurrent medical conditions included Neurofibromatosis (50 pound tumor on his left leg due to the condition.). On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criteria hospitalization and medically significant). At the time of the report, PULMONARY EMBOLISM (Pulmonary embolism) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Patient got first dose of Moderna vaccine and within 16-18 days went to emergency room and had pulmonary embolism. Was in the hospital and given heparin and eventually sent home. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of this event, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of this event, a causal relationship cannot be excluded.</p>

COVID19 VACCINE	MODERNA	1235517-1	65+ years	Unknown	<p>blood clot in his pulmonary artery and several others in his legs; blood clot pulmonary artery; shortness of breath; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (blood clot in his pulmonary artery and several others in his legs) and PULMONARY EMBOLISM (blood clot pulmonary artery) in an 82-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Family history included Factor V deficiency, Factor II deficiency and MTHFR deficiency. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (blood clot in his pulmonary artery and several others in his legs) (seriousness criteria hospitalization prolonged and medically significant), PULMONARY EMBOLISM (blood clot pulmonary artery) (seriousness criterion medically significant) and DYSPNOEA (shortness of breath). At the time of the report, THROMBOSIS (blood clot in his pulmonary artery and several others in his legs), PULMONARY EMBOLISM (blood clot pulmonary artery) and DYSPNOEA (shortness of breath) outcome was unknown. Concomitant product use was not provided by the reporter. Treatment information was not provided. Action taken with mRNA-1273 in response to the event was not applicable. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>
COVID19 VACCINE	MODERNA	1245407-1	30-39 years	Unknown	<p>a blood clot right below his lung on the left side; his chest was hurting; he couldn't breath; Second shot three weeks later; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (a blood clot right below his lung on the left side) in a 32-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history reported). In February 2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (a blood clot right below his lung on the left side) (seriousness criterion medically significant), CHEST PAIN (his chest was hurting), DYSPNOEA (he couldn't breath) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Second shot three weeks later). At the time of the report, THROMBOSIS (a blood clot right below his lung on the left side), CHEST PAIN (his chest was hurting) and DYSPNOEA (he couldn't breath) outcome was unknown and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Second shot three weeks later) had resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered THROMBOSIS (a blood clot right below his lung on the left side), CHEST PAIN (his chest was hurting) and DYSPNOEA (he couldn't breath) to be related. No further causality assessment was provided for INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Second shot three weeks later). Patient was taken to the ER (Emergency Room). Treatment Xarelto was started. Patient has Cardiologist appointment on 28-APR-2021. Company comment:Limited information regarding the blood clot, chest pain and difficulty breathing has been provided at this time and a causal relationship cannot be excluded. Inappropriate schedule of vaccine administered is unrelated to the vaccine and is not reported as specifically resulting in adverse events. This case was linked to MOD21-076660 (E2B Linked Report).; Sender's Comments: Limited information regarding the blood clot, chest pain and difficulty breathing has been provided at this time and a causal relationship cannot be excluded. Inappropriate schedule of vaccine administered is unrelated to the vaccine and is not reported as specifically resulting in adverse events. MOD21-076660:</p>

COVID19 VACCINE	MODERNA	1249559-1	Unknown	Unknown	<p>respiratory distress; cardiac arrest; pulmonary embolism; This spontaneous case was reported by a consumer and describes the occurrence of RESPIRATORY DISTRESS (respiratory distress), CARDIAC ARREST (cardiac arrest) and PULMONARY EMBOLISM (pulmonary embolism) in a 76-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Lipid metabolism disorder NOS. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 08-Apr-2021, the patient experienced RESPIRATORY DISTRESS (respiratory distress) (seriousness criterion death), CARDIAC ARREST (cardiac arrest) (seriousness criterion death) and PULMONARY EMBOLISM (pulmonary embolism) (seriousness criterion death). The patient died on 11-Apr-2021. It is unknown if an autopsy was performed. Not Provided For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. NO treatment or Concomitant medication were provided. Company Comment This is a case of sudden death in a 76-year-old female patient with a history of Lipid metabolism disorder, who died (date unknown) of respiratory distress, cardiac arrest and PULMONARY EMBOLISM after receiving first dose of vaccine. Very limited information has been provided at this time.</p>
COVID19 VACCINE	MODERNA	1249702-1	60-64 years	Unknown	<p>Bilateral pulmonary embolism; DVT; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY EMBOLISM (Bilateral pulmonary embolism) and DEEP VEIN THROMBOSIS (DVT) in a 61-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included COVID-19. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced PULMONARY EMBOLISM (Bilateral pulmonary embolism) (seriousness criteria hospitalization and medically significant) and DEEP VEIN THROMBOSIS (DVT) (seriousness criterion hospitalization). At the time of the report, PULMONARY EMBOLISM (Bilateral pulmonary embolism) and DEEP VEIN THROMBOSIS (DVT) outcome was unknown. The HCP got the vaccine several weeks after quarantine after that. After her second dose, she had a clotting issue which she had never had before. She experienced bilateral pulmonary embolism and DVT and was in the ICU twice. Action taken with the mRNA 1273 in response to the events was not applicable as the patient completed both the doses. Reporter did not provide the causality. Treatment information was not provided. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

COVID19 VACCINE	MODERNA	1254022-1	65+ years	Unknown	<p>difficulty breathing; soreness after 1st dose left arm; Clot in Lung; chest pain; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY THROMBOSIS (Clot in Lung) in an 80-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 027A21A and 046A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Heart disorder. On 03-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 29-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. In March 2021, the patient experienced PULMONARY THROMBOSIS (Clot in Lung) (seriousness criterion medically significant) and CHEST PAIN (chest pain). On 29-Mar-2021, the patient experienced VACCINATION SITE PAIN (soreness after 1st dose left arm). On an unknown date, the patient experienced DYSпноEA (difficulty breathing). On 30-Mar-2021, VACCINATION SITE PAIN (soreness after 1st dose left arm) had resolved. At the time of the report, PULMONARY THROMBOSIS (Clot in Lung), CHEST PAIN (chest pain) and DYSпноEA (difficulty breathing) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Mar-2021, Echocardiogram: normal (normal) Normal. On an unknown date, Computerised tomogram: abnormal (abnormal) Blood clot in Lung. On an unknown date, Pulmonary function test: normal (normal) came back perfect. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. On 08-Mar-2021 patient had an echocardiogram (results are not provided). Concomitant medications are not reported. No Treatment for events is provided. Based on the current available information which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, causal relationship cannot be excluded. Vaccination site pain is consistent with the known safety profile of the vaccine This case was linked to MOD-2021-084017 (Patient Link); Sender's Comments: Based on the current available information which includes a strong temporal association between the use of mRNA-1273 vaccine and onset of the reported events, causal relationship cannot be excluded. Vaccination site pain is consistent with the known safety profile of the vaccine</p>
COVID19 VACCINE	MODERNA	1254028-1	Unknown	Unknown	<p>Patient passed away; patient had blood clots in his brain/ Legs/ Lungs/ Arms; Severe hypotension; This spontaneous case was reported by a physician (subsequently medically confirmed) and describes the occurrence of DEATH (Patient passed away), THROMBOSIS (patient had blood clots in his brain/ Legs/ Lungs/ Arms) and HYPOTENSION (Severe hypotension) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included No adverse event. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced DEATH (Patient passed away) (seriousness criterion death), THROMBOSIS (patient had blood clots in his brain/ Legs/ Lungs/ Arms) (seriousness criterion death) and HYPOTENSION (Severe hypotension) (seriousness criterion death). The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment information was not provided. Company comment: This case concerns the death of a patient of unknown age and gender after administration of mrna-1273 (JLOT UNKNOWN). Very limited information regarding this event/s has been provided at this time. Further information has been requested. Critical details such as the mRNA-1273 date of administration, onset of any signs and symptoms, and date of death is lacking.; Sender's Comments: This case concerns the death of a patient of unknown age and gender after administration of mrna-1273 (JLOT UNKNOWN) . Very limited information regarding this event/s has been provided at this time. Further information has been requested. Critical details such as the mRNA-1273 date of administration, onset of any signs and symptoms, and date of death is lacking.; Reported Cause(s) of Death: Unknown cause of death</p>

COVID19 VACCINE	MODERNA	1261946-1	50-59 years	Unknown	Blood clots; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clots) in a 52-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 044A21A and 031B21a) for COVID-19 vaccination. No Medical History information was reported. On 18-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 15-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (Blood clots) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Blood clots) outcome was unknown. No treatment information was provided. No concomitant medication was reported. The patient received both scheduled doses of mRNA-1273 prior to the event(s); therefore, action taken with the drug in response to the event(s) is not applicable. Company Comment: Very limited information regarding this event/s has been provided at this time. Further information has been requested. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1264696-1	Unknown	Unknown	Blood clots; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clots) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No medical history was provided by the reporter. On 03-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. In March 2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (Blood clots) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Blood clots) was resolving. The patient took the second vaccine on the 29th or 30th of March Company Comment Very limited information regarding this event has been provided at this time. Further information has been requested. This case was linked to MOD-2021-076604 (Patient Link). Reporter did not allow further contact
COVID19 VACCINE	MODERNA	1264697-1	Unknown	Unknown	Acute necrotizing pancreatitis; Thrombosis of SMV; Thrombosis of splenic vein; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a pharmacist and describes the occurrence of PANCREATITIS NECROTISING (Acute necrotizing pancreatitis), MESENTERIC VEIN THROMBOSIS (Thrombosis of SMV) and SPLENIC VEIN THROMBOSIS (Thrombosis of splenic vein) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced PANCREATITIS NECROTISING (Acute necrotizing pancreatitis) (seriousness criterion medically significant), MESENTERIC VEIN THROMBOSIS (Thrombosis of SMV) (seriousness criterion medically significant) and SPLENIC VEIN THROMBOSIS (Thrombosis of splenic vein) (seriousness criterion medically significant). At the time of the report, PANCREATITIS NECROTISING (Acute necrotizing pancreatitis), MESENTERIC VEIN THROMBOSIS (Thrombosis of SMV) and SPLENIC VEIN THROMBOSIS (Thrombosis of splenic vein) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Based on the current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded. Very little information is available at this time. Further information has been requested.; Sender's Comments: Based on the current available information and the temporal association between product use and the start date of the events a causal relationship cannot be excluded. Very little information is available at this time. Further information has been requested.

COVID19 VACCINE	MODERNA	1269279-1	65+ years	Unknown	<p>DVT (blood clot) in leg/her leg started to hurt; Dizziness; Headache; Fever; Chills; Didn't feel well; felt bad; had to go to bed for 3 days; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEEP VEIN THROMBOSIS (DVT (blood clot) in leg/her leg started to hurt) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Blood pressure abnormal. On 02-Apr-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Apr-2021, the patient experienced VACCINATION COMPLICATION (Didn't feel well), PYREXIA (Fever) and CHILLS (Chills). On 08-Apr-2021, the patient experienced DIZZINESS (Dizziness) and HEADACHE (Headache). In April 2021, the patient experienced FEELING ABNORMAL (felt bad) and DECREASED ACTIVITY (had to go to bed for 3 days). On 18-Apr-2021, the patient experienced DEEP VEIN THROMBOSIS (DVT (blood clot) in leg/her leg started to hurt) (seriousness criterion medically significant). On 04-Apr-2021, PYREXIA (Fever) and CHILLS (Chills) had resolved. At the time of the report, DEEP VEIN THROMBOSIS (DVT (blood clot) in leg/her leg started to hurt), DIZZINESS (Dizziness), FEELING ABNORMAL (felt bad) and HEADACHE (Headache) outcome was unknown and VACCINATION COMPLICATION (Didn't feel well) and DECREASED ACTIVITY (had to go to bed for 3 days) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. The patient did not feel well for a couple of days. The events, fever and chills lasted for a day and half. On 07 Apr 2021 or 08 Apr 2021, the patient felt bad, experienced headaches and dizziness, and she had to go to bed for 3 days. On 13 Apr 2021, the patient's leg started to hurt and she ended up going to hospital. On 18 Apr 2021, the patient was diagnosed with DVT in her leg. Concomitant medications reported included drug unspecified for blood pressure. Treatment for the event included blood thinners.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However, Further information has been requested.</p>
COVID19 VACCINE	MODERNA	1269286-1	30-39 years	Unknown	<p>Clots; This spontaneous case was reported by a health care professional (subsequently medically confirmed) and describes the occurrence of THROMBOSIS (Clots) in a 38-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Apr-2021, the patient experienced THROMBOSIS (Clots) (seriousness criteria hospitalization and medically significant). The patient was hospitalized on 25-Apr-2021 due to THROMBOSIS. At the time of the report, THROMBOSIS (Clots) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications reported. No treatment information provided.; Sender's Comments: Limited information regarding the event has been provided at this time and a causal relationship cannot be excluded</p>
COVID19 VACCINE	MODERNA	1272205-1	65+ years	Unknown	<p>Blood clots; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (Blood clots) in a 68-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 011J20A and 038K20A) for COVID-19 vaccination. No Medical History information was reported. On 01-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (Blood clots) (seriousness criterion medically significant). At the time of the report, THROMBOSIS (Blood clots) outcome was unknown. Not Provided No concomitant medications were reported. The patient had no problems after her second dose. Treatment information was not provided. Action taken with mRNA-1273 in response to events was not applicable. Company comment: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.</p>

COVID19 VACCINE	MODERNA	1276796-1	Unknown	Unknown	<p>blood clot; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (blood clot) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced THROMBOSIS (blood clot) (seriousness criterion death). The reported cause of death was Clot blood. It is unknown if an autopsy was performed. The reporter stated that his wife had recently passed away from a blood clot after receiving a second dose of the Moderna COVID-19 vaccine. Treatment information was not provided. Very limited information regarding this event has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Clot blood</p>
COVID19 VACCINE	MODERNA	1294828-1	65+ years	Unknown	<p>very tired, slept all day; slept all day; She had trouble breathing; pain in back of right shoulder; found two blood clots on lungs and two in legs; found two blood clots on lungs and two in legs; there was damaged to his wife's heart too; weighed165 pounds initially and then went down to 145; This spontaneous case was reported by a consumer and describes the occurrence of DYSPNOEA (She had trouble breathing), ARTHRALGIA (pain in back of right shoulder), FATIGUE (very tired, slept all day), HYPERSOMNIA (slept all day), PULMONARY EMBOLISM (found two blood clots on lungs and two in legs), DEEP VEIN THROMBOSIS (found two blood clots on lungs and two in legs) and CARDIAC DISORDER (there was damaged to his wife's heart too) in a 79-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 028A2 or 078A2 and 028A2 or 078A2) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 31-Mar-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced DYSPNOEA (She had trouble breathing) (seriousness criterion hospitalization), ARTHRALGIA (pain in back of right shoulder) (seriousness criteria medically significant and life threatening), FATIGUE (very tired, slept all day) (seriousness criteria hospitalization, medically significant and life threatening), HYPERSOMNIA (slept all day) (seriousness criteria hospitalization, medically significant and life threatening), PULMONARY EMBOLISM (found two blood clots on lungs and two in legs) (seriousness criteria hospitalization and medically significant), DEEP VEIN THROMBOSIS (found two blood clots on lungs and two in legs) (seriousness criteria hospitalization and medically significant), CARDIAC DISORDER (there was damaged to his wife's heart too) (seriousness criterion hospitalization) and WEIGHT DECREASED (weighed165 pounds initially and then went down to 145). At the time of the report, DYSPNOEA (She had trouble breathing), ARTHRALGIA (pain in back of right shoulder), FATIGUE (very tired, slept all day), HYPERSOMNIA (slept all day), PULMONARY EMBOLISM (found two blood clots on lungs and two in legs), DEEP VEIN THROMBOSIS (found two blood clots on lungs and two in legs), CARDIAC DISORDER (there was damaged to his wife's heart too) and WEIGHT DECREASED (weighed165 pounds initially and then went down to 145) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Computerised tomogram: two blood clots on lungs and two (abnormal) two blood clots on lungs and two in legs. On an unknown date, Weight: 145 (Low) weighed 165 pounds initially and then went down to 145. The patient was hospitalized for around four days. The patient size of clots as 10 cm and 9cm in the lungs. The reporter stated that Heparin was used in the hospital and after the discharge the patient was put on Eliquis for the next 6 months. The reporter reported that the patient weighed165 pounds initially and then went down to 145 afterwards. Action taken with the mRNA-1273 is considered as not applicable. Company comment: Based on the information provided which includes a temporal association between the use of mRNA-1273 vaccine, the onset of the reported events, a causal relationship cannot be excluded.</p>

COVID19 VACCINE	PFIZER\BIONTECH	0912064-1	Unknown	Unknown	<p>had a patient receive COVID vaccine and 3 days later developed bilateral pulmonary embolisms; This is a spontaneous report from a contactable physician. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at single dose on an unspecified date for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The physician had a patient receive COVID vaccine and 3 days later developed bilateral pulmonary embolisms on an unspecified date with outcome of unknown. Have there been any similar reports of such events within short time frame of receiving the vaccine? Information about lot/batch number has been requested.; Sender's Comments: The information provided is limited and doesnot allow a full medically meaningful assessment. This case will be reassessed should additional information, especially patient age, relevant medical history, concomitant drugs and clinical course, become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>
COVID19 VACCINE	PFIZER\BIONTECH	0925634-1	Unknown	Unknown	<p>DVT; This is a spontaneous report from a contactable nurse. A patient of unspecified age and gender received BNT162B2, via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The nurse asked if there is any DVT cases reported following the administration of Pfizer-BioNTech COVID-19 Vaccine. E-transmitting duplicate AE caller already reported a DVT case post vaccination. Caller also asked ""Why is there's a statement indicating that individuals with a history of bleeding disorder or taking anti-coagulant should contact their vaccination provider? How did they prove 95 % efficacy? Why aren't antibodies produced after the 1st dose of Covid-19 vaccine?"" The outcome of the event DVT was unknown. Information on Lot/batch number has been requested.; Sender's Comments: Very limited information was provided for this individual patient, such as pre-existing medical history, suspect administration details, clinical course and relevant supportive lab data for the reported Deep vein thrombosis (DVT). Pending further details, the Company would handle this reported DVT related to the administration of BNT162B2, COVID-19 immunization, for reporting purpose. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.""</p>
COVID19 VACCINE	PFIZER\BIONTECH	1000489-1	Unknown	Unknown	<p>I may have a blood clot in my leg.; This is a spontaneous report from a contactable consumer (patient). A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not provided), via an unspecified route of administration on 20Jan2021 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient got the first dose of the vaccine on 20Jan2021 and is going to visit his doctor because they think that he may have a blood clot on his leg on an unspecified date. He wanted to know if it was okay if they give him a shot of something like contrast to see the ultrasound. The outcome of the event was unknown. Information about lot/batch number has been requested.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1000666-1	Unknown	Unknown	confirmed about a blood clot/check me for a blood clot, I didn't have one but it was kind of like a thrombosis kind of thing; Both of my legs, lower part of my legs were swollen that night when I went to bed and they got really red, almost purple red; Both of my legs, lower part of my legs were swollen that night when I went to bed and they got really red, almost purple red; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number and expiry date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The consumer stated that after the first vaccine and it might be coincidental, the patient was not sure because the patient didn't know what to expect. Both of the patient's legs, lower part of the patient's legs was swollen that night (unspecified date) when the patient went to bed and they got really red, almost purple red and the patient stayed that way for a couple of days. The patient went to see the doctor two days later and doctor confirmed about a blood clot, so they did check the patient for a blood clot; the patient didn't have one, but it was kind of like a thrombosis kind of thing. So, the doctor put the patient on antibiotics for that. The patient asked if it is related to the shot, the patient didn't know it happened the same day the patient got the shot; so, the patient didn't know about that. The outcome of the events was unknown. Information on the Lot/Batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1000670-1	65+ years	Unknown	she was hurting at her chest/ Chest pain; on her left arm hurt real bad that's what the dot on her left arm; on her left arm hurt real bad that's what the dot on her left arm; She passed away; heart attack; This is a spontaneous report from a contactable consumer. An 87-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Jan2021 at single dose for COVID-19 immunisation. Medical history included diabetes mellitus, for which she was taking a pill like an hour before she would take her meal. On Monday (Jan2021) the patient experienced was hurting at her chest/ chest pain, her left arm hurt real bad as she had a blockage in her left arm/clot on her left arm, and they wanted to put in a stent and after the surgery it went well and she all go home in two days. The patient was hospitalized in Jan2021 due to the events. She had a heart attack and that the chamber between the dividers had a hole in it and her heart tissue was too thin so much thin she couldn't repair it. The patient passed away on 26Jan2021. The patient was tested negative for COVID-19 on unknown date. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: She passed away
COVID19 VACCINE	PFIZER\BIONTECH	1031120-1	50-59 years	Unknown	Fever, Diarrhea, 1/20/21 SYMPTOMS BEGAN. ADMITTED TO HOSPITAL & CONTACTED EOH 1/27/21 WITH FEVER, CHILLS,SOB, COUGH., DIARRHEA, BLOOD CLOTS, FLUID AROUND HEART. Narrative: Other Relevant History:
COVID19 VACCINE	PFIZER\BIONTECH	1032596-1	Unknown	Unknown	On Saturday little blood clot, no liquid blood, and this morning this same; a little blood in the urine; This is a spontaneous report from a contactable consumer (the patient). A male patient (Age: 77, Unit: Unknown) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot number not provided), via an unspecified route of administration on an unspecified date (age at vaccination unknown) as a single dose for COVID-19 immunization. The patient's medical history included little blood clot, no liquid blood, 7 years ago (unspecified date in 2014). The patient's concomitant medications included fish oil and acetylsalicylic acid (ASPIRIN). The patient stated he received the first dose of the COVID shot on Thursday (unspecified date). The next morning, there was a little blood in the urine. On Saturday, little blood clot, no liquid blood, and this morning the same. The patient had this before 7 years ago. The patient asked if anyone else reported this and for information. The clinical outcome of little blood clot and a little blood in urine was unknown. Information on Lot/Batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1039940-1	Unknown	Unknown	Blood clot in her leg; This is a spontaneous report from a non-contactable consumer (patient). This female patient of unspecified age (reported only as 72) received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unknown date, for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient believed she may have a blood clot in her leg since an unspecified date. She had the second vaccine dose scheduled on an unknown date. Event outcome was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

COVID19 VACCINE	PFIZER\BIONTECH	1048205-1	Unknown	Unknown	<p>he has chronic myeloid leukemia - white blood cell count is higher; His oxygen is low; Blood clot in his legs; first dose on 19Jan2021 and second dose on 02Feb2021; first dose on 19Jan2021 and second dose on 02Feb2021; This is a spontaneous report from a contactable nurse reported for her father that an 82-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 02Feb2021 at single dose for covid-19 immunisation. Medical history included chronic myeloid leukemia (CML). Concomitant medications were not reported. Patient previously received first dose of BNT162B2 on 19Jan2021 at single dose for covid-19 immunisation. Patient received Pfizer-BioNTech COVID-19 Vaccine first dose on 19Jan2021 and second dose on 02Feb2021. Two days after second dose (04Feb2021) he had to go to the hospital - he had chronic myeloid leukemia - white blood cell count was higher (Feb2021), he had been in the hospital for the last 3 days as of 08Feb2021, his oxygen was low, had a blood clot in his legs, had a bone marrow biopsy, all on an unspecified date in Feb2021. The nurse is taking its related to this vaccine and assessed this case as not serious. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: A possible contributory effect of suspect BNT162B2 on reported events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1048691-1	Unknown	Unknown	<p>White blood cells went up greatly; Blood clots in his legs; oxygen went down/oxygen levels went down; This is a spontaneous report from a contactable consumer (patient's daughter). A male patient of an unspecified age received second dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot/batch number and expiry date were not provided), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. Medical history included he had Leukemia and was on treatment. The patient's concomitant medications were not reported. The patient took first dose bnt162b2 for COVID-19 immunization. Caller says that her father got his second COVID vaccine from Pfizer. He wound up in the hospital 3 days later. His white blood cells went up greatly and he has blood clots in his legs. They do not know what is happening. They are very worried about him. He is getting a bone marrow test today (08Feb2021). His oxygen went down yesterday (07Feb2021) and is now on oxygen. She is freaking out about it. She really thinks it has to do with vaccine. It was asked if there was any information on other people with Leukemia getting the vaccine. If what research there was on this. They need all the help and information they can get. Every minute counts as everything getting worse. He is now on oxygen as his oxygen levels went down. He is getting worse every hour. The patient underwent lab tests and procedures which included oxygen saturation: his oxygen went down yesterday/oxygen levels went down on 07Feb2021, white blood cell count: his white blood cells went up greatly on an unknown date, biopsy bone marrow: unknown results on 08Feb2021. Reporter seriousness for White blood cells went and Blood clots in his legs up greatly was hospitalization. Therapeutic measures were taken as a result of oxygen went down. The outcome of the events was not recovered. Information on the lot/batch number has been requested.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1051004-1	50-59 years	Unknown	<p>blood clot; This is a spontaneous report from a contactable consumer. A 6-decade-old female patient (in her 50's) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at a single dose as vaccine. Medical history and concomitant medications were not reported. It was noted that one of the reporter's co-worker developed a blood clot after receiving the first dose of the Pfizer vaccine on an unspecified date. Any information or data on someone developing blood clots? The outcome of the event was unknown. Information on the lot/batch number has been requested.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1051015-1	Unknown	Unknown	a heart attack; I had a blood clot in my lung; stabbing pain in chest; This is a spontaneous report from a contactable consumer. A 76 years old female patient first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection) on an unspecified date at single dose via an unspecified route of administration for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. About 30 hours after 1st dose of vaccine the patient experienced stabbing pain in chest wall, quite persistent. At first she thought was having an heart attack. Hurt too much to move. Had to lay down. Thought she had a blood clot in her lung severe for 2 days, moderate for 2 day. It was dissipated after 6 days. The patient was scheduled for second dose on 20Feb2021. The patient recovered from the events on an unspecified date. Information about Batch/Lot number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1053606-1	50-59 years	Unknown	Within a week after receiving the first round of vaccine I have developed two blood clots in my left leg.; This is a spontaneous report from a contactable consumer (patient) A 53-year-old male patient received first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number: EL3248) on 21Jan2021 at single dose via an unspecified route of administration on right arm for COVID-19 immunization. The patient didn't have medical history or concomitant medications. On an unspecified date in Jan2021 within a week after receiving vaccine patient developed two blood clots in his left leg. As treatment patient was currently on blood thinners. At the time of the reporting event outcome was unknown.
COVID19 VACCINE	PFIZER\BIONTECH	1065433-1	Unknown	Unknown	stroke; blood clot in the heart; Hospitalization with racing and irregular heart beat; Hospitalization with racing and irregular heart beat; loss of motor function; This is a spontaneous report from a non-contactable consumer. A 46-year-old male patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) (brand=Pfizer) on an unspecified date at a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. If other vaccine in four weeks was unknown. Other medications in two weeks was unknown. If covid prior vaccination was unknown. If covid tested post vaccination was unknown. Known allergies was unknown. Historical vaccine included the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) (brand=Pfizer) on an unspecified date for COVID-19 immunization. Patient experienced hospitalization with racing and irregular heartbeat, blood clot in the heart, stroke, loss of motor function on an unspecified date. Treatment included intubation. The outcome of the events was unknown. Events resulted in hospitalization, life threatening illness (immediate risk of death from the event). No follow-up attempts are possible; information about lot/batch number cannot be obtained.

COVID19 VACCINE	PFIZER\BIONTECH	1068264-1	65+ years	Unknown	<p>bilateral blood clots in legs that then went to lungs then went into BLAST crisis; bilateral blood clots in legs that then went to lungs then went into BLAST crisis; bilateral blood clots in legs that then went to lungs then went into BLAST crisis; Patient with myeloid leukaemia (CML) and WBCs abnormal received BNT162B2; Patient with myeloid leukaemia (CML) and WBCs abnormal received BNT162B2; This is a spontaneous report from a contactable consumer (patient). An 82-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Solution for injection (lot number and expiration date unknown) via an unspecified route of administration in the left arm on 02Feb2021, 13:00PM (at 82 years old) at a single dose for COVID-19 immunization. The patient was vaccinated in the Nursing Home/Senior Living Facility. The patient's medical history included myeloid leukaemia (CML) diagnosed a few months earlier, WBCs abnormal, blood pressure, and heart surgery valve repair. The patient has no known allergies. Concomitant medications included atorvastatin, carvedilol, vitamin d nos, dasatinib monohydrate (SPRYCEL) from an unknown date to help get WBCs back in normal range; cyanocobalamin (VITAMIN B12), and cetirizine hydrochloride (ZYRTEC), all were received within 2 weeks of vaccination. At 82 years old, the patient received the first dose of BNT162B2 (lot number and expiration date unknown) via an unspecified route of administration in the left arm on 12Jan2021 at a single dose for COVID-19 immunization. The patient was not diagnosed with COVID prior to vaccination and did not receive any other vaccines within 4 weeks prior to BNT162B2. It was unknown if patient was tested for COVID post vaccination. On Friday (unknown date in Feb2021), patient's WBC was 150,000 and on Saturday (unknown date in Feb2021), patient had bilateral blood clots in legs that then went to lungs then went into BLAST crisis. The adverse events resulted in emergency room/department or urgent care as well as hospitalization due to life threatening illness (immediate risk of death from the events). The patient was hospitalized for 12 days. Therapeutic measures which include steroids, blood thinners, and lots of other meds were administered. Outcome of the events ""patient's WBC was 150,000"" and ""bilateral blood clots in legs that then went to lungs then went into BLAST crisis"" was recovering. Information on the lot/ batch number has been requested.""</p>
COVID19 VACCINE	PFIZER\BIONTECH	1072538-1	65+ years	Unknown	<p>pulmonary embolism; Covid 19 PCR positive (Igg also positive) with chest x-ray consistent with Covid pneumonia, 2 weeks after 1st dose; Covid 19 PCR positive (Igg also positive) with chest x-ray consistent with Covid pneumonia, 2 weeks after 1st dose; This is a spontaneous report from a non-contactable other healthcare professional. An 82-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) first dose, lot number and expiration date unknown, via an unspecified route of administration on Jan2021 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient was admitted with pulmonary embolism and Covid 19 PCR positive (Igg also positive) with chest x-ray consistent with Covid pneumonia, 2 weeks after the 1st dose of Pfizer vaccine. The outcome of the events was unknown. No follow-up attempts are possible, information about lot/batch number cannot be obtained.; Sender's Comments: Based on the information provided by the reporter, it appears unlikely that subject product contributed to the events. The reported events may likely represent intercurrent medical conditions. Pulmonary embolism is known to be a potential complication of COVID 19 infection, including COVID 19 associated pneumonia. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including pulmonary angiogram, VQ scan and coagulation panel, counteractive treatment measures and concomitant medications. This case will be reassessed upon receipt of follow-up information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1076894-1	65+ years	Unknown	<p>multiple pulmonary emboli; This is a spontaneous report from a non-contactable consumer (patient's wife) via Medical Information team. A 72-year-old male patient received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; batch/lot number and expiration date were unknown), via an unspecified route of administration on 10Feb2021 at a single dose for COVID-19 immunization. The patient previously received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; batch/lot number and expiration date were unknown) on 19Jan2021 and experienced gradually being short of breath, which was further described as ""he would walk for 50 yards and he would be huffing and puffing."" The patient's medical history and concomitant medications were not reported. It was further reported that about 8 days after the first one, the patient started noticing gradually being short of breath. He would walk for 50 yards and he would be huffing and puffing, which was unusual, because he could walk a lot. It gradually got worse and then after the second one, it continued to get worse and he finally ended up in the hospital for 3 days with multiple pulmonary emboli on an unspecified date. The reporter was asking if this had been reported with the vaccine. The patient was hospitalized for the event multiple pulmonary emboli on an unspecified date for 3 days. The outcome of the event was unknown. No follow-up attempts are possible, information about batch/lot number cannot be obtained. No further information is expected.""</p>
COVID19 VACCINE	PFIZER\BIONTECH	1090240-1	65+ years	Unknown	<p>Cardiac arrest; Pulmonary embolus; Renal failure; Fever; Dehydration; Not eating or drinking; COVID-19 confirmed by positive COVID-19 test / COVID pneumonia; blood clot; blood pressure was low; Respiratory arrest; Respiratory failure; Hypoxemia; ventricular tachycardia; This is a spontaneous report from a contactable nurse reporting on behalf of the husband. A 71-year-old male patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EL9264) on 10Feb2021 at about 19:00 (at the age of 71 years), in left deltoid, for COVID-19 immunisation. No other vaccines were given on the same day or within 4 weeks. The patient declined flu vaccine and pneumococcal vaccine (PNEUMOVAX), he had never had another vaccine except maybe his childhood vaccines. Medical history included rotator cuff surgery and cataract removed in 2020. The patient exercised regularly, he was healthy, he walked for miles and didn't eat any non-sense, he did not eat out, he did not smoke. The patient's mother was 100 years old and fully competent. The patient had two sisters older than him, the oldest one had hypertension the second sister did not have anything that they were aware of. The patient's father lived until he was 98 years old. The patient concomitant medications were none. The patient was told to take vitamin D 50,000 units but didn't even take them (he still had 9 of them in the bottle and they gave him 13). The patient experienced fever on 11Feb2021, renal failure on 14Feb2021, pulmonary embolus on 28Feb2021, cardiac arrest on 04Mar2021, dehydration and not eating or drinking on an unspecified date in Feb2021. These events required ER visit and were reported as serious as involved hospitalization from 14Feb2021 to 04Mar2021 and as fatal events. The patient died on 04Mar2021. Clinical course of the events included the following information. The patient received the first vaccine on 10Feb2021, the next day he developed a fever. The reporter spoke with the patient's doctor who told to give the patient paracetamol (TYLENOL) thinking the fever was from the vaccine. On 12Feb2021 and 13Feb2021, the patient's temperature was 102. Then the doctor advised to take the patient to the hospital. The patient's temperature was still 102, he was in renal failure, and they had to dialyze him. The patient was otherwise healthy, the patient's last physical was in Dec2020 and the only thing it showed was that his A1C was 5.7. The patient had no cholesterol or hypertension. The doctor advised the patient to decrease sugar and carbs because the holidays were coming up. The patient's follow up was scheduled on Mar2021. The reporter felt that the vaccine has something to do with the patient renal failure. The reporter spoke with the doctors at the hospital who didn't want to commit to anything. The reporter believed this was an adverse event. The caller mentioned that she had her vaccine before and she was fine. The patient was admitted on 14Feb2021 and by Wednesday he was not eating or drinking, he was dehydrated. The patient's admitting diagnoses was elevated temperature and ruling out COVID. The patient tested positive for Covid on 14Feb2021 (COVID-19 PCR test). The patient's temperature was 99.8 and then kept creeping up, on Saturday it was 102. The caller gave the patient Tylenol cold and flu (lot TOCL001021, expiry date Oct2021) took the edge off but in three hours the temperature was back up again. The patient never complained of pain and didn't want to take Tylenol. On 15Feb2021 the patient's numbers were getting better after the fluid challenge and then his numbers kept creeping up after that. The patient had the fever a</p>

COVID19 VACCINE	PFIZER\BIONTECH	1114519-1	65+ years	Unknown	Patient received her first covid vaccine and started developing SOB and DOE 2 days later. she then was diagnosed with bilateral PE and left leg DVT on 3/6/21
COVID19 VACCINE	PFIZER\BIONTECH	1128059-1	Unknown	Unknown	blood clots found on his arm and lung; blood clots found on his arm and lung; valve blockage; This is a spontaneous report from a contactable consumer (patient's friend) via Medical Information team. A male patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; batch/lot number and expiration date were not reported), via an unspecified route of administration on 02Feb2021 as a single dose for COVID-19 immunization. Relevant medical history included COVID-19 infection from Sep2020 to an unknown date. The patient's concomitant medications were not reported. The reporter stated that the patient was due to receive his second dose the day prior reporting on 02Mar2021, and wanted to know if the patient should receive the second dose of the vaccine if he stayed longer than 3 weeks in the hospital. The patient was currently hospitalized; he received medical attention 2 weeks prior reporting on an unspecified date in Feb2021 due to some blood clots found on his arm and lung. The patient went into the hospital because he had a valve blockage on an unspecified date in Feb2021 and that the patient still had to go to rehab and might miss that 3 week window. The reporter wanted to know if a patient should restart the vaccination series if he could not receive the second dose 42 days after the first one. The patient was hospitalized for the events ""blood clots found on his arm and lung and valve blockage"" from an unspecified date in 2021. The outcome of the events was unknown. Information on the batch/lot number has been requested.""
COVID19 VACCINE	PFIZER\BIONTECH	1132489-1	65+ years	Unknown	Patient developed a pericardial effusion and PE within 2-3 days of vaccine. Unclear if related.; Patient developed a pericardial effusion and PE within 2-3 days of vaccine. Unclear if related.; This is a spontaneous report from a non-contactable physician. A 72-year-old male patient received bnt162b2 (COVID-19, Solution for injection, Batch/Lot number was not reported) via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history and concurrent medications were not reported. The patient was unclear if related. The patient experienced pericardial effusion and PE (Pulmonary embolism) within 2-3 days of vaccine on an unspecified date. The outcome of event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on known drug safety profile, there is reasonable possibility of causal association between the events pericardial effusion and pulmonary embolism and the suspect drug. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1133506-1	50-59 years	Unknown	Had a major nosebleed with blood clots; Had a major nosebleed with blood clots; This is a spontaneous report from a contactable consumer (the patient). A 54-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1, intramuscular on 08Mar2021 (Batch/Lot Number: EN6199; Expiration Date: 30Jun2021) as single dose for COVID-19 immunisation. Medical history was not reported. There were no concomitant medications. The patient had a major nosebleed with blood clots on an unknown day in Mar2021. The patient reported that he never got nosebleeds before. There was no treatment taken for the event, it stopped on itself. The outcome of the events was unknown.

COVID19 VACCINE	PFIZER\BIONTECH	1135544-1	65+ years	Unknown	DVT; This is a spontaneous report from a contactable consumer (patient). A 72-year-old male patient received first dose of BNT162B2, via an unspecified route of administration on 09Mar2021 10:00 at a single dose for Covid-19 immunization. The patient had no relevant medical history. No allergies to medications, food, or other products. No COVID prior to vaccination, he was not diagnosed with COVID-19 prior to vaccination. Concomitant medications included evolocumab (REPATHA), levothyroxine, and unspecified vitamins. No other vaccines within 4 weeks prior to the COVID vaccine. On 04Mar2021 03:00 PM (as reported), DVT occurred after receiving the first dose. Treatment received for the adverse event was blood thinner. The event resulted to doctor or other healthcare professional office/clinic visit. The event was reported as non-serious (did not result to death, not life threatening, did not cause/prolong hospitalization, not disabling/incapacitating, and not congenital anomaly/birth defect). No COVID test post vaccination. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the event was not recovered. Information on the lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1143469-1	65+ years	Unknown	phlebitis in my Right leg; small blood clot; This is a spontaneous report from a contactable nurse (patient). A 66-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in right arm on 09Feb2021 (Batch/Lot Number: EL9269) as single dose for covid-19 immunisation. Medical history included many allergies. The patient has no COVID prior to vaccination. The patient had other medications in two weeks but no other vaccine in four weeks. The patient previously had the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot: EL9263) on 20Jan2021 at 10:00 administered in the right arm for Covid-19 immunization. On 20Feb2021 at 12:00 (also reported as ""in February""), the patient had a phlebitis in her right leg, a week later (Feb2021) a vascular surgeon office did an ultrasound and found a small blood clot. The events resulted in doctor or other healthcare professional office/clinic visit. The events were treated with Eliquis BID (twice a day) for 45 days. The patient was not tested for COVID post vaccination. The outcome of the events was not recovered.; Sender's Comments: A causal relationship between BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) and the event thrombosis cannot be excluded based on temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate .""
COVID19 VACCINE	PFIZER\BIONTECH	1143483-1	40-49 years	Unknown	Blood clot; Unable to use arm at all; This is a spontaneous report from a contactable consumer (patient, self-reported). A 49-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number and expiry dates were not provided), via an unspecified route of administration, in arm left, on 09Mar2021 02:15 AM, as single dose for COVID-19 immunization. Patient's medical history included Fibromyalgia. Concomitant medications were not reported. Patient was not diagnosed with COVID, prior vaccination. Patient has not been tested for COVID, post vaccination. Patient did not receive other vaccine in four weeks of vaccination. On an unknown date in Mar2021, patient had Blood clot and patient was unable to use arm at all. Patient resulted in Emergency room/department or urgent care, Disability or permanent damage in Mar2021. Patient did not receive treatment for adverse events. Seriousness of the events reported as hospitalization and disability. Outcome of the events was not recovered. Information about lot/batch number has been requested.

COVID19 VACCINE	PFIZER\BIONTECH	1148783-1	65+ years	Unknown	Clot; Swelling and pain in left foot, ankle, and calf; Swelling and pain in left foot, ankle, and calf; This is a spontaneous report received from a contactable consumer (Patient's son). A 81-years-old female received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, batch/Lot number not reported), via an unspecified route of administration, administered in Arm Left on 02Feb2021 (believes in afternoon) at single dose for covid-19 immunisation. The patient medical history and concomitant medication were not reported. Patient previously took history vaccine included shingles shot received on Nov2020 and Flu shot typically gets every year. On 02Jan2021, patient received first dose of COVID vaccine (BNT162B2) for covid-19 immunisation. The patient experienced severe swelling and pain in foot, calf, and ankle on the left side shortly after the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) was administered. She was hospitalized and placed on Xarelto for treatment by her cardiologist and was scheduled to follow-up to have other procedures performed as deemed needed. Doctor advised patient had a clot and was put on Xarelto. An angio and cath was suggested to see if she had something closing up in her. Patient was going back in a few weeks to see about the clot. she never had this clotting concern before, and this was all new right after the second COVID vaccine. Swelling and pain in left foot, ankle, and calf was either 04Feb2021 or 05Feb2021. she first noticed left foot was swollen. she stated her foot was sore. It was unknown if it went to her ankle and then from there. It was stated that the pain and swelling was better. She was informed by the nurse administering the COVID vaccine that second dose would be a little bit stronger. The patient underwent lab tests and procedures which included MRI on 15Feb2021 and diagnosed the clot. The outcome of the event Clot was unknown. For other events was recovered on unspecified date in 2021. Information about Batch/Lot number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1151417-1	Unknown	Unknown	blood clots in his left legs and also some in his lungs.; blood clots in his left legs and also some in his lungs.; This is a spontaneous report from a contactable consumer (patient) received via Medical Information Team. A 64-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 02Mar2021 (Lot number was not reported) as single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient reported that he had to go to the emergency room (ER) where they discovered blood clots in his left legs and also some in his lungs in Mar2021. The events were serious, the patient was hospitalized for 2 days. Therapeutic measures were taken as a result of the events and the patient was placed on blood thinners. The patient outcome of the events was unknown. Information on the lot/batch number has been requested.

COVID19 VACCINE	PFIZER\BIONTECH	1151451-1	Unknown	Unknown	<p>if it was a lung issue or blood issue, such as blood clots; nervous system was affected; weakness on her leg; had very tight calf muscles; eye pain; have difficulty breathing; she was dragging her feet, could not take the next step.; had ""such a tight feeling"" of the calf, and a little bit of pain to it; nauseous; if it was a lung issue or blood issue, such as blood clots; whether the injection was done in the wrong location; her arm was very itchy and a red papule-like round rash developed, it was pigmented,; her arm was very itchy and a red papule-like round rash developed, it was pigmented,; her arm was very itchy and a red papule-like round rash developed, it was pigmented,; it was ""highlighted"" and ""dot-like""; had a sharp pain, and tingling or pain-like sensation at the fingertips/she was going ""through a world of pain"", and from the arm down to the side of body.; had a sharp pain, and tingling or pain-like sensation at the fingertips; a fever too, 99.4°F at one time and over 100°F for a day or so; This is a spontaneous report from a contactable consumer. This consumer (patient) reported for self that the female patient of an unspecified age received second dose of bnt162b2 (BNT162B2,PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EN6200, Expiration Date: 30Jun2021) via an unspecified route of administration on 05Mar2021 at single dose for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient previously took first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot#: EL9262, expiration date: 31May2021) for covid-19 immunization for covid-19 immunization, rabies vaccine and experienced pain. The patient experienced if it was a lung issue or blood issue, such as blood clots on Mar2021 with outcome of unknown, nervous system was affected on Mar2021 with outcome of unknown, weakness on her leg on Mar2021 with outcome of unknown, had very tight calf muscles on Mar2021 with outcome of unknown, eye pain on Mar2021 with outcome of unknown, have difficulty breathing on Mar2021 with outcome of unknown , she was dragging her feet, could not take the next step on Mar2021 with outcome of unknown , had ""such a tight feeling"" of the calf, and a little bit of pain to it on Mar2021 with outcome of unknown, nauseous on Mar2021 with outcome of unknown, if it was a lung issue or blood issue, such as blood clots on Mar2021 with outcome of unknown, whether the injection was done in the wrong location on Mar2021 with outcome of unknown, her arm was very itchy and a red papule-like round rash developed, it was pigmented on Mar2021 with outcome of unknown, her arm was very itchy and a red papule-like round rash developed, it was pigmented on Mar2021 with outcome of unknown, her arm was very itchy and a red papule-like round rash developed, it was pigmented on Mar2021 with outcome of unknown, it was ""highlighted"" and ""dot-like"" on Mar2021 with outcome of unknown , had a sharp pain, and tingling or pain-like sensation at the fingertips/she was going ""through a world of pain"", and from the arm down to the side of body on Mar2021 with outcome of unknown , had a sharp pain, and tingling or pain-like sensation at the fingertips on Mar2021 with outcome of unknown. The patient underwent lab tests and procedures which included body temperature: 99.4 fahrenheit on Mar2021, body temperature: 100 fahrenheit on Mar2021. The consumer reported that ""Who makes the vial label? What syringe did they use to give her the vaccine? How big was it? Where is the vaccine administered? Did we make a second batch with ""much less"" side effects? She</p>
COVID19 VACCINE	PFIZER\BIONTECH	1153501-1	50-59 years	Unknown	<p>blood clot in her lungs; shortness of breath; chest pain; This is a spontaneous report from a non-contactable consumer. A 51-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 03Mar2021 as single dose for COVID-19 immunisation. Medical history included obesity and inactivity. The patient's concomitant medications were not reported. On an unspecified date, patient experienced blood clot in her lungs and was hospitalized on 14Mar2021. Patient also experienced shortness of breath and chest pain on an unspecified date. She was treated with anticoagulant therapy for the event ""blood clot in her lungs"". Outcome of event ""blood clot in her lungs"" recovered on an unspecified date while for all other events was unknown. No follow-up attempts are Possible. Information on lot/batch cannot be obtained.""</p>

COVID19 VACCINE	PFIZER\BIONTECH	1154074-1	50-59 years	Unknown	<p>Blood clot/very large blood clot from his thigh to his calf; Joint pain; chills; he can't even walk now; leg pain; This is a spontaneous report received from a contactable consumer (patient's wife). A 57-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number: EN6202), via an unspecified route of administration, on 25Feb2021 (at the age of 57-years-old), at a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The consumer stated she's asking on behalf of her husband. He received his first dose of Pfizer-BioNTech COVID-19 Vaccine on 25Feb2021 and had Joint pain and chills after that (on unspecified date in 2021) he was diagnosed with Blood clot (unspecified date in 2021); she stated he had no history of similar health issues and wanted to know if it could be directly linked to this vaccine. The wife further reported that it's dramatically changing his life, he can't even walk now. He had the Covid vaccine on 25Feb2021 and he has no history of blood clots. He developed a leg pain (on unspecified date in 2021) which was odd and they thought that maybe it was some arthritis or something like that. They went to the orthopedist and he was being treated for what the orthopedist thought was a bakers cyst. But then they discovered it was a very large blood clot from his thigh to his calf. They would like to know about this. They have been looking into what he had experienced, and it seems very unusual. It just seems too coincidental that this happened after the Covid vaccine. The emergency room doctor of course shut them down immediately and said that the Covid vaccine never would have done this. But the patient's doctor yesterday said that there are too many unknowns to say for sure that the Covid vaccine didn't cause this. She is not saying that they are against the Covid vaccine, but they are concerned. The patient is on blood thinners now and they just need to know if there is a possible correlation. She had heard on the world news that there is a connection after receiving the (company name) Covid vaccine and now they are shutting this vaccine down in (region name). She saw on the news last night they were asking if there is a correlation with the Pfizer and (company name) Covid vaccines and this. It is very concerning. They have been trying to do research and there is nothing that you can find. The only thing that they did see online was about the doctor that died of a blood disorder in (state name), he had thrombocytopenia. The patient is going to be sent to see a vein doctor. She stated that he has a lot of things ahead of him and he is too young to be dealing with all of this. They are going to be following up with the vein doctor and she would like to have this information when the vein doctor calls later today. The reported adverse events resulted to an emergency room and physician office visit (went to the orthopedist). The patient received corrective treatment as response to the reported events. Outcome of the events was unknown.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1154104-1	Unknown	Unknown	<p>Clot blood; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced clot blood on an unspecified date with outcome of unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1158711-1	65+ years	Unknown	<p>Blood clots; This is a spontaneous report from a non-contactable consumer through a Pfizer sales representative. An 80-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number and expiration date were not reported) as a single dose, with route of administration and therapy date unspecified, for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient had blood clots. The patient was hospitalized on an unspecified date due to the reported event. The outcome of the event, blood clot, was unknown. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1162139-1	Unknown	Unknown	He was diagnosed with multiple blood clots in his lungs/ clots may have appeared in his leg and went to his lung; bed ridden; pain in left side; This is a spontaneous report from a contactable consumer (the patient). A 70 year old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH, COVID-19 MRNA VACCINE)), via an unspecified route of administration on 06Feb2021 (Lot number: UNKNOWN) as a single dose for COVID-19 vaccination. The patient medical history and concomitant medications were not reported. Historical vaccination included BNT162B2 (PFIZER-BIONTECH, COVID-19 MRNA VACCINE), dose 1 via an unspecified route of administration on 16Jan2021 (Lot number: UNKNOWN) as a single dose for COVID-19 vaccination. The patient reported that he received the first dose of the Pfizer-BioNTech Covid-19 vaccine on 16Jan2021. On 06Feb2021 he received the second dose of the vaccine. Twelve days later he was diagnosed with multiple blood clots in his lungs, and from ""15Feb2021 to 16Feb2021"" he was hospitalized. He was prescribed to take Eliquis (Apixaban) a blood thinner, at 5 mg tablets for 6 months. He also reported that during that period (first part of Jan and part of Feb) he was bedridden because he had a lot of pain in his left side and it would not let him get out of bed, so he was on bed for a while. His primary care doctor told him that the clots may have appeared in his leg and went to his lung. The patient would like to know if any participant developed blood clots during the clinical trials of the vaccine. The clinical outcome of the events was unknown. Information on the lot number has been requested.""
COVID19 VACCINE	PFIZER\BIONTECH	1166696-1	65+ years	Unknown	right thigh pain Treatment : lovenox 80 sery
COVID19 VACCINE	PFIZER\BIONTECH	1174114-1	Unknown	Unknown	blood clot; This is a spontaneous report from a contactable consumer(patient). A female patient of an unspecified age received BNT162B,(PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. prednisone (PREDNISONE), route of administration, start and stop date, batch/lot number and dose were not reported for allergies Medical history included weakened immune systems and ongoing allergies. It was reported that patient wants to know if there is any reported interactions between the use of prednisone and receiving the COVID-19 vaccine manufactured by Pfizer. She was informed that the vaccine might not work as well for patients taking prednisone. The patient has been on Prednisone for 10 years, caller heard that when the patient has been on Prednisone for that long the vaccine does not work. The patient is taking Prednisone to treat some allergies. Patient also has blood clots and wants to know if patients with a history of allergies should take the COVID-19 vaccine manufactured by Pfizer, and how could she know if she would have an allergic reaction towards the vaccine. The action taken in response to the event for Prednisone was unknown. The outcome of the event was unknown. Information on the batch/lot number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1174174-1	Unknown	Unknown	I broke a pimple and came liquid after taking the pimple out, it came a little thing like clear and then it came like blood; it was like a clot; broke a pimple; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration on 06Mar2021 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. Consumer stated, ""I am kind of concerned because I was showering myself like 30 minutes ago, well I was cleaning my face and well you like night routine and I broke a pimple that I didn't have and came liquid after taking the pimple out, it came a little thing like clear and then it came like blood not too much for sure, then I realized that the blood that came out wasn't liquid, it was like a clot. I cleaned it with a t-shirt and I was able like to move it. So I am kind of concerned because I got my first dosage of the Pfizer vaccine on March the 6th, I am about to get my second dosage this Saturday and as you know and everyone should know right now what's going on with this (name) and (name) vaccine and then what everyone is talking about, it's impossible to not be concerned about the side effects."" The event clot blood was assessed as serious (medically significant). The outcome of the events was unknown. Information on lot/batch number has been requested.""

COVID19 VACCINE	PFIZER\BIONTECH	1174276-1	30-39 years	Unknown	<p>fatigue/so tired, he can barely can move; silver dollar rash at the injection site; his whole calf was constricted, felt like the muscle was separating inside, compared it to the same feeling of DVT; he is limping today; feeling pain in arm; left arm hurts so bad that he can hardly move it; fever; This is a spontaneous report from a Pfizer-sponsored program, received from a contactable consumer (patient, self-reported). A 39-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number: ER8730; Expiration date was not reported), via an unspecified route of administration, administered in Arm Left on 24Mar2021 17:00 as SINGLE DOSE for COVID-19 immunization. Medical history included DVT (deep venous thrombosis) 3 years ago in his right calf/DVT of calf from 2019 to an unknown date (Right Calf; DVTs in his calf and had treatment with Eliquis and got off of that, had an ultrasound to check that it was gone); broke his ankle on an unspecified date in 2019; being in a tourniquet too long (DVT (deep venous thrombosis) 3 years ago in his right calf, from being in a tourniquet too long, was in an operation, was treated with ultrasound); normally when something hurts that bad, he has a softball size bruise on his arm, he has lived and had bruises like that before; Operation (DVT (deep venous thrombosis) 3 years ago in his right calf, from being in a tourniquet too long, was in an operation, was treated with ultrasound/rebreak his ankle and put rods and screws in). The patient's concomitant medications were not reported. It was reported that feeling pain in arm on 24Mar2021, fatigue on 25Mar2021, fever on an unknown date in Mar2021, silver dollar rash at the injection site on 25Mar2021. He reported that he had DVT (deep venous thrombosis) 3 years ago in his right calf, from being in a tourniquet too long, was in an operation, was treated with ultrasound. This morning (25Mar2021), his whole calf was constricted, felt like the muscle was separating inside, compared it to the same feeling of DVT that he had those years back. Patient reported that he thought he might be having allergic reaction. He was so tired, he can barely can move, he had a silver dollar size rash on his arm and his arm hurts so bad that he can hardly move it. He stated that this was weird and he has it every now and then, but it is really bad today. He states that 3 years ago he had DVTs in his calf and had treatment with Eliquis and got off of that, had an ultrasound to check that it was gone. He stated that his leg and it hurts so bad. It felt like has phantom clots in the same the muscles are separating again, like the muscle is trying to tear itself in half. Caller asks, the vaccine won't cause blood clots, will it?. Described about Tired, he couldn't get out of bed and he had been laying there for 3 hours this morning. Stated he ate dinner and went to bed. Stated that he works a full time job doing HVAC and goes to school full time so he could've been tired last night and not noticed it, because he is always tired, but today was different. Described about Left Arm Hurts, that it felt like when you play dead arm, that is when a person socks another kid in a certain spot, felt like he was hit with a bat in that spot. Hurt bad and he was surprised how bad it hurt. When he got the injection, he felt nothing. Now he feels like he fell down on his arm. Within a few hours he noticed it and thought it would probably go away. States that he was checking to see if he had a big ole bruise, and that when he noticed the rash. He stated that normally when something hurts that bad, he has a softball size bruise on his arm. States that he has lived an had bruises like that before.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1175195-1	18-29 years	Unknown	<p>experiencing passing a ton of clots; I washed my face, it got extremely red; This is a spontaneous report from a contactable consumer (patient). A 20-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported) at the age of 20-year-old, via an unspecified route of administration, administered in the left arm on 19Jan2021 13:00 as single dose for COVID-19 immunisation. The patient was not pregnant at the time of vaccination. Medical history included lupus and idiopathic thrombocytopenic purpura (ITP). Concomitant medications included mycophenolate mofetil (CELLCEPT), esomeprazole magnesium (NEXIUM), medroxyprogesterone acetate (DEPOPROVERA), and propranolol; all taken for an unspecified indication, start and stop date were not reported. The patient has known allergies to rituximab and amoxicillin. As a woman, the patient was having a lot of blood clots being passed. The patient doesn't get a period because of depo, but for some reason, she was experiencing passing a ton of clots on an unspecified date. Also, after the first dose, when she washed her face, it got extremely red on an unspecified date in 2021 (She did the same in the days before and that didn't happen). The patient underwent lab tests and procedures which included Covid test: negative on an unspecified date. The outcome of the events was unknown. No treatment was received for the events. The patient received the second dose of BNT162B2 on 11Feb2021 for COVID-19 immunisation administered at the left arm. Information on the lot/batch number has been requested.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1178287-1	Unknown	Unknown	blood became a clot; pimple; This is a spontaneous report received from a Pfizer sponsored program received from a contactable consumer (patient). A male patient of an unspecified age received bnt162b2 (BNT162B2 reported as Pfizer Covid-19 vaccine), dose 1 via an unspecified route of administration on 06Mar2021 (Batch/Lot number was not reported) as a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported that he received Pfizer Covid-19 vaccine first dose on 06Mar2021, and second dose will be on Saturday 27Mar2021. While showering, he broke his pimple on Mar2021 then tried to remove it using the tissue and the blood became a clot. The outcome of the events was unknown. Information on the lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1178288-1	Unknown	Unknown	he has thrombosis in leg; This is a spontaneous report received from a Pfizer sponsored program. A contactable consumer (patient himself) reported that a male patient of an unspecified age received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as a single dose for COVID-19 immunisation. Medical history included metastatic cancer in the lungs (he's taking chemotherapy) and heart problems from an unknown date. The patient's concomitant medications were not reported. The patient was due the next day for the 2nd dose of the Pfizer vaccine. He was asking if he can take his pre-scheduled medication, especially he's taking chemotherapy because he has metastatic cancer in the lungs. Due also to the nature of him having heart problems, he had thrombosis in leg and he's taking blood thinner since an unspecified date. He was asking if he should stop the medication or if he can take the blood thinner before the 2nd dose. Outcome of the event was unknown. Information on the lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1190936-1	65+ years	Unknown	Hypertensive crisis at 180/95; Vascular thrombosis; Head is spinning; This is a spontaneous report from a contactable consumer (patient). A 67-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number: EN6198), via an unspecified route of administration in left arm, on 16Mar2021, at a single dose, for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had no known allergies to medications, food, or other products. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The most recent COVID-19 vaccine was administered in a hospital facility. In Mar2021, the patient's head was spinning, there was a hypertensive crisis at 180/95 for 2 times, and there may be a vascular thrombosis. It was unknown if treatment was received for the adverse events. The events were considered non-serious by the patient. Since the vaccination, the patient has not been tested for COVID-19. The outcome of the events was unknown.
COVID19 VACCINE	PFIZER\BIONTECH	1190993-1	Unknown	Unknown	blood clots in his lungs; Lot of pain in his left side; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 2 via an unspecified route of administration on 06Feb2021 as single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient previously took bnt162b2 for COVID-19 immunisation and had lot of pain in his left side (1 st dose-During period (first part of Jan and part of Feb) he was bedridden). It was reported that caller received the first dose of the Pfizer-BioNtech Covid-19 vaccine on 16Jan2021, in the hospital. On 06Feb2021 he received the second dose of the vaccine. Twelve days later he was diagnosed with multiple blood clots in his lungs, from Feb2021 he was hospitalized, he was prescribed to take Eliquis (Apixaban; blood thinner) 5mg tablets for 6 months. During that period (first part of Jan and part of Feb) he was bedridden because he had a lot of pain in his left side and it would not let him get out of bed, so he was on bed for a while. His primary care doctor told him that the clots might have appeared in his leg and went to his lung. Caller would like to know if any participant developed blood clots during the clinical trials of the vaccine. Therapeutic measures were taken as a result of blood clots in his lungs. The outcome of events was unknown. Information on the lot/batch number has been requested.

COVID19 VACCINE	PFIZER\BIONTECH	1191842-1	65+ years	Unknown	Thrombosis pulmonary; This is a spontaneous report from a contactable consumer. A 69-year-old female patient received bnt162b2 (BNT162B2), via an unspecified route of administration on 09Feb2021 as SINGLE DOSE for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient experienced thrombosis pulmonary. Outcome of the event was unknown. Information on the lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1191875-1	Unknown	Unknown	Had a couple of PEs (pulmonary embolism); This is a spontaneous report from a non-contactable physician via a Pfizer sales representative. A patient of unspecified age and gender received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient previously took the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date for COVID-19 immunization. The patient had a couple of PEs (pulmonary embolism) on an unspecified date with outcome of unknown. No follow-up attempts are possible, information about lot/batch number cannot be obtained.; Sender's Comments: The information available in this report is limited and does not allow a medically meaningful assessment of the case. The company cannot completely exclude a causal relationship between the pulmonary embolism and suspect vaccine BNT162B2. Additional information regarding relevant medical history, underlying conditions and concomitant medications will aid in comprehensive assessment of the case. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1191897-1	Unknown	Unknown	blood clot on the lungs; This is a spontaneous report from a Pfizer sponsored program. Received from a contactable consumer. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient already got the 1st dose of the vaccine and have a 2nd dose schedule tomorrow. They wanted to reschedule the 2nd dose because the patient was in the hospital and might have a blood clot on the lungs. Treatment was received. The outcome of the event was unknown. Information on the batch/lot number has been requested.

COVID19 VACCINE	PFIZER\BIONTECH	1191916-1	Unknown	Unknown	<p>she had developed what she believes is a blood clot in her leg; This is a spontaneous report from a contactable other healthcare professional (nurse) via medical information team. The contactable consumer reported for her mother that a 77-year-old female patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, formulation: solution for injection) intramuscularly on an unspecified date as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient previously took her first dose of bnt162b2, on an unspecified date for covid-19 immunisation. The patient's mother received the second dose of the covid vaccine yesterday morning. When the caller saw her mother last night, she had developed what she believes is a blood clot in her leg on an unknown date. The reporter would like to know whether a blood clot is a possible side effect from the covid vaccine. The patient did not receive any type of treatment for the adverse event. The outcome of the event was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported event of Thrombosis leg due to temporal relationship. However, the reported event may possibly represent intercurrent medical condition in this elderly patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including venous doppler of lower extremities and coagulation panel, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1191960-1	40-49 years	Unknown	<p>Blood clot in LAD which caused a STEMI; Blood clot in LAD which caused a STEMI; This is a spontaneous report received from a contactable consumer (female). A 49-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot Number: EN6208), first dose via an unspecified route of administration, administered in Arm Left on 20Mar2021 08:15 (at the age of 49 years old), single dose for covid-19 immunisation. Medical history included hypothyroidism, Penicillin allergy, both from an unknown date. The patient was taking unspecified concomitant medications within 2 weeks of vaccination. The patient experienced blood clot in lad which caused a STEMI on an unspecified date (reported as 03Mar2021 15:15, for clarification since before vaccination date). The outcome of the events was unknown. The events was assessed as serious, causing hospitalization, disability and was life-threatening. Treatment for the events were Balloon in LAD / clot buster. The patient underwent lab tests and procedures which included COVID-19: negative on 03Mar2021. Patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Information on Lot/Batch number was available. Additional information has been requested.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1201947-1	Unknown	Unknown	<p>On March 18 sore on the right arm, 3/19 chills,fever, cough, taste was off by salty every tasted like pure salt even a piece of candy. Back pain on lower back and stomach pains and inflammation of the stomach. Started with very painful back pain went to the doctor and gave him antibiotics and pain medicines and since he was not recovering with the medication they admitted him to the hospital on 4/9 with a blood clot in the portal vain causing no draining from liquids to the intestines and was placen on blood thinners</p>
COVID19 VACCINE	PFIZER\BIONTECH	1203725-1	Unknown	Unknown	<p>10 days after receiving my first Pfizer shot I suffered a stroke that was caused by a blood clot. I was unable to speak for a short time the morning of 4/1/2021 and went to emergency room at. My speech had already returned and I was no longer having symptoms. There were numbers tests and scans run and it was confirmed that I had a stroke that was caused by a blood clot. There were no obvious issue present to why I would have had this happen.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1204788-1	65+ years	Unknown	<p>Diverticulitis arteries; I had a blood clot after ultra sound; sore arm/Feel sore arms after the first dose; spinal nerve damage/Spinal nerve pain; Legs are burning hot now; Pain felt in calf and thigh; Bone density test/Ultra sound bad; This is a spontaneous report from a contactable consumer(patient). An 84-years-old female patient received BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 1 intramuscular, administered in Arm Left on 01Feb2021 11:30 (Batch/Lot Number: EN5318) as SINGLE DOSE, dose 2 via an unspecified route of administration, administered in Arm Left on 22Feb2021 11:30 (Batch/Lot Number: EN6200) as SINGLE DOSE for covid-19 immunization. Medical history included angina from 2002 and ongoing, She says she has angina, and if she would have beating problems can she take a Nitro, cholesterol, depression from 2008 to an unknown date, blood pressure, anxiety from 2018 to an unknown date, arthritis from 1998 and ongoing Illness/AE: Arthritis Onset Date: 1998-2002 Stop Date: Ongoing , hypertension from 2002 and ongoing, blood cholesterol increased from 2002 and ongoing, ongoing urinary tract infection On and off, coronary artery disease from 2005 to an unknown date On and off, Family medical history included Mother coronary artery disease Died on 18Oct1967 and Father 1936 other. Concomitant medications included amlodipine taken for blood pressure abnormal from 2017 to an unspecified stop date; atorvastatin taken for blood cholesterol abnormal from 2002 to an unspecified stop date; bupropion taken for depression from 2008 to an unspecified stop date; buspirone taken for anxiety from 2008 to an unspecified stop date; carvedilol taken for blood pressure abnormal from 2002 to an unspecified stop date, 2x a day carvedilol 12.5. On an unspecified date, the patient experienced diverticulitis arteries, had a blood clot after ultrasound, sore arm/feel sore arms after the first dose, spinal nerve damage/spinal nerve pain, legs are burning hot now, pain felt in calf and thigh, bone density test/ultrasound bad. The patient underwent lab tests and procedures which included blood test: unknown results, computerized tomogram: diverticulitis arteries- On and off, investigation: unknown results. Comments: Going to pain clinic. On always, ultrasound scan: bad on Comments: Ultrasound bad, urine analysis: unknown results on comments: on and off. Treatment received for the events sore arm/feel sore arms after the first dose and spinal nerve damage/spinal nerve pain. Outcome of all events was unknown Follow-up (29Mar2021): This is a follow-up report combining information from duplicate reports 2021138557 and 2021162095. The current and all subsequent information will be reported under manufacturer report number 2021162095.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1205190-1	Unknown	Unknown	<p>her veins were swollen and she had blood clot.; her veins were swollen and she had blood clot.; severe earache; severe headache; her mouth and throat were on fire.; her mouth and throat were on fire.; This is a spontaneous report from a non-contactable consumer (other HCP) via medical information team. A patient of unknown age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number and expiration date were not reported) via unknown route of administration on 09Mar2021 as single dose for covid-19 immunisation. Reportedly, patient got the first dose of the Pfizer COVID-19 vaccine on 09Mar2021. After that, she had developed severe earache, severe headache, her mouth and throat were on fire. Few days later, her veins were swollen and she had blood clot. She was also afraid to take her medication, Eliquis, since there may be more adverse events from that medication. Patient was scheduled for her second shot of the Pfizer COVID-19 vaccine today, 20Mar2021. She was told that the adverse events after the second dose of the vaccine are worse than the first dose. She has also read that people die from the vaccine. She wants to cancel her appointment today. She wanted to know if the vaccine would be 80-85% effective after a single dose. She wanted to know if she would be ok with just one dose of the vaccine. No PQC was present. The outcome for the events was unknown. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the information currently available, a possible contributory role of the suspect vaccine BNT162B2 in triggering the onset of thrombosis and other events cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1205261-1	65+ years	Unknown	<p>Diarrhea; Vomiting; Weak; Found Slumped Against the Wall; Low Potassium; MRI Found Multiple Small Emboli in Brain; thrown more clots; Aphasia; Difficulty Walking; potassium dropped and she went into A-Fib and threw clots; potassium dropped and she went into A-Fib and threw clots; has problems with recent memories; confusion; food sensitivities; This is a spontaneous report from a contactable physician (patient's daughter). An 86-year-old female patient received her second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not provided) at the age of 86-years-old, via an unspecified route of administration on 24Mar2021 at 14:00 at single dose for COVID-19 immunization. Medical history included high blood pressure diagnosed in 1971 (reported as 50 years ago) and ongoing; type 2 diabetes in 2011 (reported as 10 years ago) which resolved in 2019 (about 2 years ago) after the patient lost some weight; she had an episode of A-Fib in 2019 when her potassium was low (lower than the current hospitalization), once the potassium was corrected, her A-Fib resolved. The physician stated that patient has shrunk and was now about 5 foot 2 inches. Clarified that this has not recently occurred since the vaccine; stated it was happening just with age. The patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date were not provided), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's concomitant medications were not reported. The patient did not have any issues with the first dose of the vaccine. She received her second vaccine dose on 24Mar2021. The physician spoke with the patient on Friday, 26Mar2021, and the patient was fine. On Saturday, 27Mar2021, the patient had an episode of diarrhea, vomiting and was weak. The lady cleaning the patient's house found her slumped against the wall. The physician met them at the hospital and said the patient seemed okay. They thought it was just an issue from her potassium being low on Mar2021, so they gave her that. The hospital did a CT scan that showed nothing on Mar2021. The hospital did an MRI of the head that showed multiple small emboli in the brain on Mar2021. The physician believed that the patient must have thrown more clots because she became aphasic on Mar2021 and could not name things. The patient also had difficulty walking on Mar2021. The physician felt it was important to call and report this since she has heard of people throwing clots with vaccines. The physician did not know if the events were related to the vaccine. The patient was in the hospital for 7 days (as reported). She was now able to walk with some assistance. The patient's son thought that the patient was okay when he went to see her. Since the reporter was a physician, she knew which questions to ask the patient and saw that she still had some problems. The patient could remember some things but has problems with recent memories on an unspecified date in 2021. She also has some confusion on an unspecified date in 2021, such as she thought she was in a boat hospital. The physician was uncertain if the vomiting and diarrhea was somewhat better. They were wondering if the patient has some food sensitivities (2021). The patient also had carotid studies done in the hospital on Mar2021 and they were fine. They believed that patient's potassium dropped, and she went into A-Fib and threw clots on Mar2021. The clots must have come from the heart valves since the carotid studies were fine and if the clots had been in her legs, they would've</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1215649-1	Unknown	Unknown	<p>Patient advised she took COVID-19 Vaccine and formed blood clots in leg; This is a solicited report from a non-Pfizer sponsored program: -CW2891702, received from a contactable consumer, based on information received by Pfizer from manufacturer (manufacturer control number: BMS-2021-032881), license party for apixaban. This 86-year-old female patient was involved in a patient support program. The patient (patient ID: (ID)) received APIXABAN. The report describes a case of THROMBOSIS (Patient advised she took COVID-19 Vaccine and formed blood clots in leg). Co-suspect products included Covid-19 Vaccine for an unknown indication. On an unknown date, the patient started APIXABAN (unknown route), (unspecified dose and frequency). On an unknown date, the patient experienced THROMBOSIS (seriousness criterion medically significant). The action taken with APIXABAN (Unknown) was unknown. At the time of the report, THROMBOSIS outcome was unknown. For APIXABAN (Unknown), the reporter did not provide any causality assessments. This report was received from consumer. The patient received therapy with apixaban and COVID-19 Vaccine for unknown indication. Follow-up is unable to be performed. Medical evaluation comment: This patient had blood clots in the leg after apixaban therapy. Based on the limited information regarding medical history, event details, treatment details, it cannot be ascertained that the suspect drug contributed to the reported event. The reporter's assessment of the causal relationship of the event Thrombosis leg with the suspect products was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment. Amgen's assessment: the event, Thrombosis leg, was assessed as unrelated to apixaban. No follow-up attempts are possible; information about batch number cannot be obtained.; Sender's Comments: As there is limited information in the case provided, the causal association between the event of thrombosis and the suspect vaccine BNT162B2 cannot be excluded. Based on known mechanism of action of the drug, the event of thrombosis is assessed as not related to Apixaban. The case will be reassessed once new information is available. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1224396-1	65+ years	Unknown	<p>hoped she wasn't having a heart attack; Elevated Pulse/high pulse/pulse was 165 beats per minute/climbed up to 195; Drenched in sweat/sweating/sweating like a dog in the middle of the night; Wasn't feeling well; Tightness in chest; Cough; Sinuses congested; Sore; Puffy, bubbled up arms, inflamed; Puffy, bubbled up arms, inflamed; Feverish/felt hotter than usual; Really, really tired/wiped out tired; so sleepy; Sore Arm/her arm started to hurt; Nauseous; Sore Throat/throat hurts; eyes half closed/eyes closing; Puffy Face; blood clot; This is a spontaneous report from a contactable consumer (patient). A 72-year-old female patient received the first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number ER8733, expiry date: unknown), via an unspecified route of administration, on 29Mar2021 11:45, as single dose, for COVID-19 immunisation. Medical history included ongoing latex allergy (developed welts where the straps met the skin) diagnosed 20-30 years ago; ongoing dye allergy (developed warm soreness to leg, tightness in the chest, could not breathe) diagnosed many years ago; sulphite allergy (diagnosed about 1975-1980; cannot eat processed foods, bleached foods, frozen pre-made foods; tries to eat only single item foods; last anaphylactic reaction after eating olive oil at a restaurant because it had sulphites in it; Mother was possibly allergic to sulphites; Son also allergic to sulphites); and blood pressure that runs low. The patient previously took epinephrine and experienced epinephrine allergy; ciprofloxacin (CIPRO) and experienced Cipro Allergy (eyes closed, got puffy, couldn't breathe); amoxicillin for abscessed tooth and had a reaction because of the sulphites in it; epinephrine (EPIPEN) and experienced epinephrine allergy (does not use it anymore); plantago ovata (METAMUCIL) which she then found out the orange one had sulphites. Historical vaccine included flu shot for immunization and she experienced 104-degree temperature and was sick as a dog and she went to the emergency room (she had flu shot maybe 3 times). Ongoing concomitant medication included multivitamins. The patient got her first dose of BNT162B2 on 29Mar2021 at 11:45. On the same day, once she got home, she became really, really tired/wiped out tired; was so sleepy; experienced sore arm/her arm started to hurt; was nauseous; had sore throat/throat hurt; eyes half closed/eyes closing and puffy face. On 30Mar2021, the patient experienced elevated pulse/her pulse got too high/pulse was 165 beats per minute/climbed up to 195. Her heart rate was 194 at some point for a couple of minutes then stayed at 165 for a long time. She hoped she wasn't having a heart attack. She had tightness in her chest, wasn't feeling good and was coughing. She stayed in her bed to wait out her symptoms. These lasted for 10 minutes (as reported). She started meditating hoping her heart rate would decrease and it did after about 15-20 minutes. The patient also felt feverish/felt hotter than usual. Before she took the vaccine on 29Mar2021, her temperature was at 96. She stated that her temperature usually runs low as 95-06 degrees. She also felt like her sinuses were congested; was sore; had puffy, bubbled up arms, inflamed. The patient hoped it was not a blood clot she developed. At the time of the report, the patient stated that her heart rate was 61 beats per minute, earlier it was in the 70s; and her temperature was at 96.3. Her second dose is scheduled on 19Apr2021 and mentioned that if these were her reactions with the first dose, she is questioning getting the second dose. The outcome of ""blood clot"", ""hoped she wasn't having a heart attack"", ""Wasn't feeling well"",</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1224636-1	65+ years	Unknown	<p>Blood clots after the 2nd dose; Blood clot split and some went into side of lung; This is a spontaneous report from a contactable consumer (patient). A 73-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration in the right arm, on 14Feb2021 at 15:45 (Lot Number: EL3247) (at the age of 73-years-old) as a single dose for COVID-19 immunisation. The patient had no medical history, family history, or concomitant medications. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: E10142 (as reported)), in the right arm, on 24Jan2021 at 15:45 (at the age of 73-years-old) for COVID-19 immunisation. The patient did not receive any other vaccines within four weeks prior to the vaccination. The patient experienced blood clots after the 2nd dose and blood clot split and some went into side of lung in Feb2021, which required hospitalization from 27Feb2021 to 28Feb2021. The clinical course was reported as follows: The patient stated he did not know what date the blood clots occurred and can't tell when that happened, but it was maybe a few weeks after the second dose of the vaccine. He stated that one blood clot is in the right leg near the calves and the blood clot broke and split some and went up into the side of his lung as it was detected in a doppler on 27Feb2021. The patient was hospitalized from 27Feb2021 to 28Feb2021. The doppler was performed as soon as he went into the emergency room and they went through a series of tests with unknown results on 27Feb2021 and 28Feb2021. The patient stated that the right leg is bigger than the other leg and they told him it might stay that size and may not go down. The patient is now on apixaban (ELIQUIS) 5 mg for the rest of his life. In the beginning, they gave him an unspecified shot in his stomach, then after that he began taking apixaban at two pills in the morning and two pills at night, then they cut him down to 1 pill in the morning and 1 pill in the evening, and he started it right when he went into the hospital immediately. Therapeutic measures were taken as a result of the event as aforementioned. The clinical outcome of blood clots after the 2nd dose and blood clot split and some went into side of lung was unknown.</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1224670-1	50-59 years	Unknown	<p>This is a spontaneous report received from a contactable consumer (patient). A 54-year-old male patient (height: 193cm, weight: 99.79kg) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number: EN6207) via an unspecified route of administration at right upper arm on 18Mar2021 18:00 (54-year-old at time of vaccination), at single dose, for COVID-19 immunization. The patient's medical history included blood pressure, teeth cleaned (Shortly before the shot, went to the dentist to have teeth cleaned. Directly from Dentist went to pharmacy. Went to pharmacy's Drive Thru to pick up a little antibiotic from the dentist. It was 4 capsules of Amoxicillin. He was supposed to take the Amoxicillin before the dentist office visit, but he forgot to do that. Therefore, soon as he left the dentist office he went to pharmacy to pick it up so he could take it. While he was there, was offered the COVID 19 vaccine and that it was the last shot). Concomitant medications included atenolol tablet from 2016 (been taking for 5 years) and ongoing for blood pressure, and ascorbic acid/ cyanocobalamin/ ergocalciferol/ nicotinamide/ pyridoxine hydrochloride/ retinol/ riboflavin/ thiamine mononitrate (ONE-A-DAY). No additional vaccines administered on same date. No history of all previously immunizations. No prior vaccinations within 4 weeks. He got the shot Thursday and by Sunday, many different side effects were coming in. He has had side effects from the COVID VACCINE, but initially he does not want to file report, just thinks that everyone needs to get the shot. He does not have complaints. He is wondering how long the side effects will last, and when they go away. States that he is being treated as he has gone to the doctor's. Also states that he made an appointment with the doctor and almost went to the emergency room a couple of times. Right after the shot, he was getting in the car and his right leg started hurting (on 18Mar2021). It didn't go away for a couple of days. It went away but then noticed his shoes started feeling funny. He wasn't looking at his feet, put his shoes on they felt tight. Then he started to look at feet more. Below his knees, his legs are swollen. Swelling started within 2 to 3 days after the vaccine. The swelling is really severe when standing. Everybody at work has seen how sick he is and his legs. Swelling in the legs has him concerned, thinking maybe it's a blood clot. He was given medicine and would like to see it go away. He keeps his legs up. He has other side effects (all in Mar2021) and is having flu like symptoms. He basically has the flu. He has never had the flu shot. This is the first flu shot (He referred to the COVID vaccine as the flu shot as documented. However, confirmed suspect product as Pfizer covid vaccine) he has had that he knows of. He is questioning if he should get the second shot. He feels a little dizzy. Quick questions get him confused and that it comes and goes. Lungs felt full, gasping for air: not now but, since the doctor gave him antibiotics (unspecified injections, he was given 2 shots at the doctor's office, one in each arm), his lungs felt full. At times he was gasping for air. It went away but thought he was going to die. Now when he gets winded, it feels like he has a dry cough. Gets winded easily. The doctor ordered him an inhaler, Symbicort, but it was very expensive, so he did not get it at that time. He never picked it up because it was too much money. The fluid is not there anymore and he does not feel like he needs this as does not feel like it needs to be cleared. He is having wheezing. He can now take deeper breaths. Fatigue: initially, that he was feeling tired within 1 or 2 days, but he did not recall the next day feeling that way (later stated it was within</p>
COVID19 VACCINE	PFIZER\BIONTECH	1224703-1	Unknown	Unknown	<p>Some blood clot on both of her legs; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as a single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced some blood clot on both of her legs on an unspecified date. It was reported that patient would have a procedure on Friday and then she was going to go for the vaccination on Saturday. they would like to know if there was any problem for her to have the vaccination done. The outcome of the event was unknown. No follow-up attempts are possible; information about batch number cannot be obtained.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1227979-1	Unknown	Unknown	<p>got clots all over the body; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on an unspecified date as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced got clots all over the body in Mar2021 and he passed away. Pfizer has not been reporting any effects of blood clot. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: got clots all over the body</p>

COVID19 VACCINE	PFIZER\BIONTECH	1227980-1	50-59 years	Unknown	<p>Blood Clot/The Blood clot was in the legs and went to his lungs; Blood Clot/The Blood clot was in the legs and went to his lungs; fell; Leg pain; This is a spontaneous report from a contactable consumer. A 51-year-old male patient received his first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 27Mar2021 (Batch/Lot Number: EP6955) as single dose for covid-19 immunisation. Medical history included thrombosis from 2020 to an unknown date, it was Months ago in 2020, He was prescribed a medicine for blood clots, but since then he has had no issues, anxiety from an unknown date and unknown if ongoing. Her brother in law had anxiety about even getting the vaccine. The patient experienced leg pain on Mar2021 , pulmonary thrombosis, leg thrombosis and fall on an unspecified date. The patient died on 02Apr2021. An autopsy was not performed. The clinical course was the following: The Blood clot was in the legs and went to his lungs, his leg never got red or anything and it was a blood clot. He was having such bad leg pain, it's too bad, had there been some sort of warning, he would have thought to wait till next year. There was nothing the day he got vaccine, but that night his leg started hurting, his girlfriend said let me go get a cold wrap and she wrapped it, he's a farmer. He wakes up the next day and his leg is still hurting, the 3rd day it goes on, his leg still hurting and no one is thinking it a blood clot, he calls the doctor and tells the doctor his leg is hurting, they suggest ibuprofen for inflammation, the next day thought maybe it's better, by Friday he was making breakfast, fell and died. With his girlfriend she said what's going on, and he went straight to hospital, they said the clot in his leg went to the lung. The Blood clot when it was in the leg it never got hot, red, or anything like that. He had the vaccine in the morning and on that same day the leg pain started later that night. It Started out with Leg Pain, she does not know if it was right or left but it was just one leg.; Reported Cause(s) of Death: Thrombosis pulmonary; Thrombosis leg; Fall; Leg pain</p>
COVID19 VACCINE	PFIZER\BIONTECH	1235798-1	Unknown	Unknown	<p>Blood clots in legs where old injury was; This is a spontaneous report from a contactable consumer (patient). A 83-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. Medical history included patient had an old leg injury several times in the past, which was fine. The patient's concomitant medications were not reported. The patient experienced blood clots in legs where old injury was on an unspecified date with outcome of unknown. Received call from consumer who stated she had a speech impediment. She was calling about the Pfizer COVID vaccine. She had the 1st shot. She had an old leg injury several times in the past, which was fine. This time it had big blood clots that appeared since the vaccine. She was afraid to go for second shot. She would like some guidance about getting second shot because she was afraid to go get it. Unable to confirm if speech impediment was prior to receiving vaccine or after. No further details provided. Information on the lot/batch number has been requested.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1235808-1	Unknown	Unknown	Brain clot: acute thrombosis of the Left transverse sinus, left sigmoid sinus and upper left internal jugular vein cerebral sinus venous thrombosis; This is a spontaneous report from a contactable nurse. A 39-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), dose 1 via an unspecified route of administration, administered in Arm Left on an unspecified date (reported as 19Mar2021; pending clarification). (Batch/Lot Number: EL9266) as single dose for covid-19 immunization. The patient's medical history was not reported. The patient was not pregnant at the time of vaccination. Concomitant medication included desogestrel, ethinylestradiol (PIMTREA) taken for an unspecified indication, start and stop date were not reported. The patient previously took diflucan and experienced allergy. The patient experienced brain clot: acute thrombosis of the left transverse sinus, left sigmoid sinus and upper left internal jugular vein cerebral sinus venous thrombosis (hospitalization, disability, life threatening) on 10Mar2021 12:45. The patient was hospitalized for brain clot: acute thrombosis of the left transverse sinus, left sigmoid sinus and upper left internal jugular vein cerebral sinus venous thrombosis for 6 days. The patient was treated with Heparin and Coumadin. The event resulted in: doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event), disability or permanent damage. The patient received the second dose of bnt162b2 on an unspecified date (reported as 18Mar2021; pending clarification), lot number: EN6204, on right arm. The patient was recovering from the event. The patient was not diagnosed with COVID prior to vaccination. Patient has not been tested for COVID post vaccination.; Sender's Comments: Based on the current available information, the events occurred prior to BNT162B2 administration (this information need be clarified). The reported events are considered as an intercurrent or underlying condition which is not related to the suspected drug at this time. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1235824-1	Unknown	Unknown	blood clot; This is a spontaneous report from a contactable consumer (patient) from a Pfizer-sponsored program. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date (Lot number was not reported) at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced blood clot (life threatening) on an unspecified date. Event as reported: Patient had a blood clot due to our vaccine. The outcome of the event was unknown. Information about lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1254584-1	50-59 years	Unknown	3 days after the first dose I developed a blood clot in my right calf, never had one before, no trauma, i am very active; This is a spontaneous report from a contactable consumer (patient). A 59-year-old male patient received first received first dose of bnt162b2 (Pfizer, Formulation: Solution for injection, Lot Number: EP 7534b) via an unspecified route of administration, administered in left arm on 13Mar2021 11:00 at a single dose for covid-19 immunization. Medical history and known allergies were none. Concomitant medication included rivaroxaban (XARELTO). The patient developed a blood clot in his right calf 3 days after the first dose, never had one before, no trauma, he was very active on 16Mar2021 07:00. No covid vaccination was taken prior. No covid tested post vaccination. Blood thinner for the clot was given as the treatment. The outcome of the event was not recovered.

COVID19 VACCINE	PFIZER\BIONTECH	1254765-1	65+ years	Unknown	<p>blood clot in her right ankle; varicose vein in her right ankle and it started to hurt; varicose vein in her right ankle and it started to hurt; ankle on her right side started swelling; This is a spontaneous report from a contactable consumer (patient). A 66-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration on arm left on 26Feb2021 14:00 (Batch/Lot Number: EN6198) as SINGLE DOSE for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient previously took the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EM9809 and expiry date: 30Jun2021) on left arm on 05Feb2021 for covid-19 immunisation. The patient experienced blood clot in her right ankle, varicose vein in her right ankle and it started to hurt, ankle on her right side started swelling, all on an unknown date. All events caused patient physician office visit. Treatment received for all events. It is reported that she is calling about the Covid 19 vaccine. She wanted to report that she developed a blood clot in her right ankle. She went to the doctor yesterday on 06Apr2021. She would like to add she has no prior history of any type of blood issues. The doctor she saw thought that the blood clot and the Covid 19 vaccine could be related but would not commit to saying so directly. She started having issues about 6 days after the second Covid 19 vaccine. She doesn't exactly remember when, maybe the 04Mar2021 or 05Mar2021. She ignored the issues attributing them to over exercising. She reached a point where she couldn't ignore the issues anymore and went to the doctor. Caller clarifies she has a varicose vein in her right ankle and it started to hurt then her ankle on her right side started swelling. She only payed attention to her ankle when it got worse. The last 3 weeks have been awful. She would like it known that she does not lead a sedimentary lifestyle. She rides her bike 60 miles a week and walks 10 miles a week. She's always moving. This is unusual for her. The doctor she saw diagnosed her with a blood clot and he did a sonogram in his office. She has been prescribed Xarelto 15mg tablets. Take 2 tablets twice daily for the first 21 days then on the 22nd day start taking one 20mg tablet once daily. The patient underwent lab tests and procedures which included sonogram: unknown result on 06Apr2021. The outcome of the all events was unknown.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1255100-1	30-39 years	Unknown	<p>Dvt and PE; Dvt and PE; This is a spontaneous report from a contactable other healthcare professional (patient). A 38-year-old non-pregnant female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date (at the age of 38-years-old) as a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced deep vein thrombosis (DVT) and pulmonary embolism (PE) on 31Mar2021. The patient underwent lab tests and procedures which included SARS-COV-2 test: negative on an unspecified date. The event resulted in the Emergency room/department or urgent care. Therapeutic measures were taken as a result of both events [rivaroxaban (XARELTO)]. The outcome of the events was recovered on an unspecified date. Information on the lot/batch number has been requested.; Sender's Comments: Based on known drug profile and available information it is unlikely that the reported deep vein thrombosis and pulmonary embolism were causally related to BNT162B2. These are intercurrent medical conditions. Case will be reassessed if additional information is received. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1255342-1	65+ years	Unknown	<p>blood clot; Right leg swelled and achy; Right leg swelled and achy; This is a spontaneous report from a contactable nurse (patient). A 67-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot Number: EP7534),dose 1 via an unspecified route of administration, administered in Arm Left on 16Mar2021 (at the age of 67years) as single dose for Covid-19 immunization. Medical history included ongoing Beta thalassemas. The patient's concomitant medications were not reported. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient stated she has never had a problem with vaccinations, and she gets the flu vaccine every year. The patient reported that after the first injection coincidentally she did develop a blood clot in her lower leg. She thinks that it was due to a plane ride, but she has never had a blood clot before the injection. She added that she had the first dose on 16Mar2021 and developed a clot in a week. She further clarified that she got her first injection on 16Mar2021 and realized when she went on a flight, which is not that far she developed that clot and was having problems shortly after flight home on 24Mar2021 where her leg swelled up and she is on blood thinners since she went to the emergency room. She added that she developed the clot sometime between that flight and 02Apr2021. She had a doppler study on an unspecified date and it showed a blood clot. She stated that the outcome was she does not have the blood clot (as reported) but she will be on blood thinners and she needs to follow up on her scan to see if the clot issue is resolved but she will not have a doppler scan for another month or two and the blood thinner she is taking is Xarelto. She also stated that her right leg swelled up and it felt like a log. She reported it felt achy and swollen quite a bit from knee down and her leg was achy. It started between 24Mar2021 and by time she went to the emergency room she was not getting better. She had her symptoms for a week and toward the end of the week she thought she had a blood clot since it was not getting better it just got worse. She added that right now it is not swollen but she has been supine, and she does believe that it is better. The outcome of events was recovering. (As reported ""outcome is unknown but pretty sure it has improved because of the blood thinners""./She stated she does not think it has resolved because it takes time for clots to resolve./She added that right now it is not swollen but she has been supine, and she does believe that it is better.) The reporter stated for the seriousness criteria for event blood clot: she believes as a nurse that any blood clot is extremely dangerous, and she was not hospitalized but obviously a blood clot is serious, and she could have ended up with pulmonary embolism. The seriousness for events right leg swelled and achy was reported as medically disabling. Causality assessment: Patient stated for the blood clot she has doubts if it was related to the vaccine but is it something that should be known about; for the leg swelling and achy she has doubts but it could have been the plane ride.; Sender's Comments: Based on the current available information, the reported events are most likely related to an intercurrent or underlying condition which is unlikely related to the suspected drug. The plane ride may provide an explanation for the events. The case will be reassessed if additional information becomes available.""</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1255460-1	60-64 years	Unknown	<p>blood clot on the left side of neck; This is a spontaneous report from a contactable HCP (patient). The patient was a Respiratory Therapist. A 60-year-old male patient received his second dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EN6206), via an unspecified route of administration on 03Apr2021 (at the age of 60-years-old) as single dose for COVID-19 immunisation. The patient took the first dose of BNT162b2 (lot number EN6199) on an unspecified date for COVID-19 immunisation. Medical history included high cholesterol and hypertension from an unknown date and unknown if ongoing. Concomitant medications included nebivolol hydrochloride (BYSTOLIC) taken for hypertension, start and stop date were not reported; rosuvastatin taken for blood cholesterol increased, start and stop date were not reported. The patient experienced blood clot on the left side of on an unspecified date in Apr2021. The event was treated with blood thinner. Patient thought it was called Xarelto because they called him on 07Apr2021. He was not sure how to spell that. Treatment was started on 07Apr2021. Consumer stated he first started having symptoms on the night of the injection. On an unspecified date in Apr2021 the patient did the ultrasound and that's when they found blood clot and he just got the results back. Recently, may be 2 weeks before reporting, patient had routine blood work and it was normal. It was nothing abnormal. The outcome of event was unknown.; Sender's Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of event Clot blood cannot be excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1255462-1	Unknown	Unknown	<p>Her husband got a heart attack a week after the first dose; there are blood clots on his legs; This is a spontaneous report from a Pfizer-sponsored program. A male patient of an unspecified age received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 24Mar2021 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The reporter stated that her husband got a heart attack a week after the first dose and there are blood clots on his legs on an unspecified date. Outcome of the events was unknown. Information on the Lot/Batch number has been requested.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1255463-1	Unknown	Unknown	<p>Developed like a blood clot, black and blue in the arm; Developed like a blood clot, black and blue in the arm; This is a spontaneous report from a non-contactable consumer (patient). A patient of unspecified age and gender received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot Number and Expiration Date were not reported), via an unspecified route of administration, on an unspecified date, at a single dose, for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient previously took the first dose of BNT162B2 for COVID-19 immunization. The patient was calling about the side effects of Pfizer COVID-19 vaccine and was wondering. The patient got the first and second vaccine of Pfizer for COVID-19. After the second dose of vaccine on an unspecified date, the patient developed like a blood clot, black and blue in the arm. The patient wanted to ask if this is a rare side effects or common. The outcome of the events was unknown. No follow-up attempts are possible; information about batch number cannot be obtained. No further information is expected.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1255545-1	Unknown	Unknown	<p>I am bleeding heavily because I am getting blood clots and stuff like that; I am bleeding heavily because I am getting blood clots and stuff like that; Right side of face, my tongue inside is very swollen and irritated; Lot of pain in my joints and in my bones; Right side of face, my tongue inside is very swollen and irritated; Right side of face, my tongue inside is very swollen and irritated; Lot of pain in my joints and in my bones; This is a spontaneous report from a contactable consumer (patient) A patient of unspecified age and gender received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration on an unspecified date (Lot number FN6200) as SINGLE DOSE for covid-19 immunisation; axitinib (INLYTA), via an unspecified route of administration from an unspecified date (Batch/Lot number was not reported) to an unspecified date, at 2 DF, 1x/day (two pills a day ) for renal cancer; pembrolizumab (KEYTRUDA), route of administration, start and stop date, batch/lot number and dose were not reported for renal cancer; zoledronic acid (ZOMETA), route of administration, start and stop date, batch/lot number and dose were not reported for bone disorder . The patient received the first dose of BNT162B2 on unknown date (Lot number CL9265). The patient medical history was not reported. The patient's concomitant medications were not reported. The patient stated ""I got a clear cell renal cancer. And I am taking a combination Inlyta okay which is your drug and Keytruda and I also have also taken Zometa that is for the bones and I have had two Pfizer Vaccines (Unspecified Vaccines) for it.I am getting terrible side effects from either the Inlyta or the Keytruda. I am bleeding very heavily and the right side of face, my tongue inside is very swollen and irritated. I am getting a lot of pain in my joints and in my bones. I am bleeding heavily because I am getting blood clots and stuff like that. I just wonder if there is anything that I have been taking Inlyta two pills a day and I have taken probably 80 pills from the start. So, if there is anything to mitigate what's going on. The action taken with axitinib , and pzoledronic acid embolizumab was unknown.""The outcome of the event was unknown""</p>
COVID19 VACCINE	PFIZER\BIONTECH	1255613-1	30-39 years	Unknown	<p>Unreported possible deep vein thrombosis day after 1st shot. 4 days of thinking I had a charley horse. Confirmed pulmonary embolism on 24Feb2021; Unreported possible deep vein thrombosis day after 1st shot. 4 days of thinking I had a charley horse. Confirmed pulmonary embolism on 24Feb2021; Unreported possible deep vein thrombosis day after 1st shot. 4 days of thinking I had a charley horse. Confirmed pulmonary embolism on 24Feb2021; This is a spontaneous report from a contactable consumer. This consumer (patient) reported that the 37-year-old female patient received first dose of bnt162b2 (BNT162B2), via an unspecified route of administration, administered in Arm Left on 19Jan2021 11:00 AM at single dosefor covid-19 immunization. The patient took second dose of bnt162b2 (BNT162B2), via an unspecified route of administration, administered in Arm Left on 09Feb2021 at single dose for covid-19 immunisation. The patient medical history was not reported. Pas drug event included Known allergies: cinnamon. Concomitant medication(s) included amfetamine aspartate, amfetamine sulfate, dexametamine saccharate, dexametamine sulfate (ADDERALL) taken for an unspecified indication, start and stop date were not reported; ethinylestradiol, norethisterone acetate (JUNEL) taken for an unspecified indication, start and stop date were not reported. The patient previously took cinnamon and experienced drug hypersensitivity. The patient experienced ""unreported possible deep vein thrombosis day after 1st shot. 4 days of thinking i had a charley horse. confirmed pulmonary embolism on 24Feb2021"" (medically significant, life threatening) on 20Jan2021 09:00 with outcome of recovering, ""unreported possible deep vein thrombosis day after 1st shot. 4 days of thinking i had a charley horse. confirmed pulmonary embolism on 24Feb2021"" in Jan2021 with outcome of recovering. The patient underwent lab tests and procedures which included COVID tested post vaccination Nasal Swab, PCR (sars-cov-2 test): negative on 03Feb2021, negative on 10Feb2021, negative on 17Feb2021, negative on 10Mar2021, negative on 17Mar2021, negative on 26Mar2021, negative on 05Apr2021, negative on 07Apr2021. Therapeutic measures were taken as a result of ""unreported possible deep vein thrombosis day after 1st shot. 4 days of thinking i had a charley horse. confirmed pulmonary embolism on 24Feb2021"". Facility type vaccine was Hospital. No other vaccine in four weeks. AE resulted in Life threatening illness (immediate risk of death from the event). Ae treatment included treatment for Pulmonary Embolism, medications. No COVID prior vaccination. Information on Lot/Batch number has been requested.""</p>

COVID19 VACCINE	PFIZER\BIONTECH	1255683-1	Unknown	Unknown	painful little clot in her front leg; pain/ache; shortness of breath like wheezing; shortness of breath like wheezing; This is a spontaneous report from a contactable consumer via a Pfizer sponsored program. A female patient (consumer) of an unspecified age received first dose of BNT162B2 (Pfizer COVID-19 Vaccine, Formulation: Solution for injection, Lot number and expiration dates were not reported), via an unspecified route of administration on 26Mar2021, at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient reported that she had the first dose 26Mar2021 and scheduled for the second dose on 21Apr2021, which was more than 21 days. Caller read the news about the adverse events with (Other company vaccine). They experienced pain/ache and shortness of breath like wheezing on an unspecified date in 2021. They also had a painful little clot in her front leg on an unspecified date in 2021. They wants to know if she can take the second dose. The outcome of the events was unknown. Information about lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1255692-1	60-64 years	Unknown	Blood Clot; This is a spontaneous report from a contactable nurse. A 60-year-old female patient (no pregnant) received her second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EN6208), intramuscular at the age 60-year-old at arm right on 11Mar2021 at single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient previously received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EN6200), intramuscular at the 60-year-old at right arm on 19Feb2021 for COVID-19 immunisation and experienced pneumonia. There was no other vaccine in four weeks. Facility type vaccine was reported as public health clinic/administration facility. The patient experienced blood clot on Mar2021 after 2nd. The patient was hospitalized for event for 5 days. Adverse event resulted in doctor or other healthcare professional office/clinic visit, emergency room/department or urgent care, hospitalization, life threatening illness. The patient received the treatment for event. The outcome of event was unknown.; Sender's Comments: Based on information available, a possible contribution role of the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) to the onset of event clot blood cannot be completely excluded. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021422806 same patient/product, different dose and event
COVID19 VACCINE	PFIZER\BIONTECH	1255693-1	18-29 years	Unknown	Blood Clot formed in lung; cough; This is a spontaneous report from a contactable consumer (patient). A 24-year-old female patient received BNT162B2 (lot number: EL3246) second dose on 10Feb2021 (24-year-old) on left arm at single dose for COVID-19 immunisation. Medical history included Hypothyroidism. Patient had allergy to Hydrocodone, Oxycodone and Acyclovir. Patient is not pregnant. No covid prior vaccination. Concomitant medications included sertraline and levothyroxine. No other vaccine in four weeks. Historical vaccine included bnt162b2 (lot number: EL3246) on 16Jan2021 09:00 AM (vaccinate age 24 years old) first dose on left arm for covid-19 immunization. Facility type vaccine was Hospital. Patient had Blood Clot formed in lung on 17Feb2021 12:00 AM and cough a week in Feb2021 after second shot. Event resulted in Emergency room/department or urgent care, Life threatening illness (immediate risk of death from the event)]. Patient received Medication as treatment. The outcome of events was Recovered with lasting effects. No covid tested post vaccination.

COVID19 VACCINE	PFIZER\BIONTECH	1255703-1	Unknown	Unknown	<p>Patient died; portal vein thrombosis; thrombocytopenia; This is a spontaneous report from a contactable physician. A 50-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on an unspecified date as SINGLE DOSE for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. The patient experienced portal vein thrombosis and thrombocytopenia 2 weeks after first Pfizer vaccine. Patient died. The patient died on an unspecified date. It was not reported if an autopsy was performed. The outcome of the events portal vein thrombosis and thrombocytopenia was unknown. The outcome of the event unknown cause of death was fatal. Information on the lot/ batch number has been requested.; Sender's Comments: The information available in this report is limited and does not allow a medically meaningful assessment of the case. Based on temporal association, a causal association between the reported events and BNT162B2 cannot be fully excluded. Case will be reassessed when additional information is available including medical history and concomitant drug information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and investigators, as appropriate. ; Reported Cause(s) of Death: Patient died</p>
COVID19 VACCINE	PFIZER\BIONTECH	1255710-1	Unknown	Unknown	<p>DVT; multiple bilateral pulmonary embolisms/blood clots in both lungs after being sent to the ER; one blood clot still in my leg/ blood clots in both lungs; This is a spontaneous report from a contactable Other HCP. A 41-year-old female reported that she received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number BL9269), intramuscular into the left arm on 08Feb2021 at single dose for COVID-19 immunization. No COVID prior vaccination. Medical history included type 1 diabetes mellitus, Hashimoto's Disease. Concomitant medication(s) included metformin (METFORMIN) and levothyroxine (LEVOTHYROXINE) . The patient had received the first dose of BNT162B2 on 19Jan2021. About a week before the second dose, she self-diagnosed with a calf injury due to extreme pain that felt like a constant cramp that lasted until her second dose. After the second dose, she was hospitalized 5 days (16Feb2021-20Feb2021) with multiple bilateral pulmonary embolisms/blood clots in both lungs after being sent to the ER by a nurse practitioner, and told that her previously self diagnosed leg injury was really DVT. She actually left the hospital with one blood clot still in her leg.Hospital's Cardiac ICU by physician's transport because her case was too to be treated at (Withheld). The patient underwent lab tests and procedures which included antiphospholipid antibodies (unknown date): unknown results (won't be in until mid-Jun because it requires testing 12 weeks apart)- tested negative for genetic conditions that could have caused the clots , had a negative COVID nasal swab test on 16Feb2021.The events DVT and pulmonary embolism resulted in Emergency Room visit /Physician office visit .The event ""DVT"" was treated with Heparin, still on blood thinner. The outcome of the event DVT was recovering.; Sender's Comments: Based on vaccine-event chronological association causality between reported events and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be excluded. . The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s) : US-PFIZER INC-2021427569 same patient, and drug different dose""</p>

COVID19 VACCINE	PFIZER\BIONTECH	1255713-1	40-49 years	Unknown	<p>DVT; multiple bilateral pulmonary embolisms; rash; hives on my lower abdomen; calf injury due to extreme pain that felt like a constant cramp; This is a spontaneous report from a contactable Other HCP (patient) . A 41-years-old no pregnant female patient received bnt162b2 (BNT162B2), dose 1 via an unspecified route of administration, administered in Arm Left on 19Jan2021 16:30 (Batch/Lot Number: EL1283) as SINGLE DOSE for covid-19 immunisation. Age at vaccination: 41 years. No other vaccine in four weeks. No COVID prior vaccination Medical history included type 1 diabetes mellitus from an unknown date and unknown if ongoing, Hashimoto's Disease from an unknown date and unknown if ongoing. Concomitant medication(s) included metformin (METFORMIN) and levothyroxine (LEVOTHYROXINE). The patient experienced DVT followed by multiple bilateral pulmonary . The clinical course was reported as follows: ""Within 5 hours of the first dose I got a 3"" in diameter rash and hives on my lower abdomen, which I reported when receiving my second dose. About a week before the second dose, I self-diagnosed myself with a calf injury due to extreme pain that felt like a constant cramp that lasted until my second dose. After the second dose, I was hospitalized 5 days (16Feb2021-20Feb2021) with multiple bilateral pulmonary embolisms/blood clots in both lungs after being sent to the ER by a nurse practitioner, and told that my previously self diagnosed leg injury was really DVT - I actually left the hospital with one blood clot still in my leg. Hospital's Cardiac ICU by physician's transport because my case was too to be treated at (Withheld). I am lucky to have survived this-please warn people of the symptoms"" The patient underwent lab tests and procedures which included antiphospholipid antibodies (unknown date): unknown results (won't be in until mid-Jun because it requires testing 12 weeks apart)- tested negative for genetic conditions that could have caused the clots, sars-cov-2 test: negative on 16Feb2021. The events DVT and pulmonary embolism resulted in Emergency Room visit /Physician office visit . The event ""DVT"" was treated with Heparin, still on blood thinner. The patient received the second dose on 08Feb2021 left arm (Lot#BL9269). The outcome of the event DVT was recovering. The outcome of the other events was unknown; Sender's Comments: Based on vaccine-event chronological association a causal relationship between events Deep vein thrombosis, Pulmonary embolism and Pain in extremity and BNT162B2 vaccine cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. Linked Report(s) : same report/patient, different dose/AE""</p>
COVID19 VACCINE	PFIZER\BIONTECH	1255731-1	Unknown	Unknown	<p>Hot a fever then full blown covid; Hot a fever then full blown covid; blood clot; organ failure; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer reported that a male patient of an unspecified age received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunisation . The patient medical history and concomitant medications were not reported. Previously on an unknown date, the patient received the first dose of BNT162B2 vaccine. On an unspecified date, the patient experienced hot a fever then full blown COVID, blood clot and organ failure leading to patient death on an unknown date. It was not reported if an autopsy was performed. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected; Reported Cause(s) of Death: Drug ineffective; Covid-19; Blood clot; Organ failure</p>

COVID19 VACCINE	PFIZER\BIONTECH	1261825-1	18-29 years	Unknown	<p>Experienced life-threatening blood clots in both lungs (bilateral pulmonary embolism); chills; flu-like symptoms; difficulty breathing; chest pain; nerve pain in neck; severe rib pain; spitting up blood constantly; severe aches and pains all over my body; This is a spontaneous report from a contactable consumer. A 19-year-old non-pregnant female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in Arm Left on 08Apr2021 15:45 (Batch/Lot Number: ER8737) (at age of 19-year-old) as single dose for COVID-19 immunisation. Medical history included Polycystic Ovarian Syndrome, and eczema. Concomitant medications included ethinylestradiol, ferrous fumarate, norethisterone acetate (BLISOVI FE 1/20) and hydroxyzine, both taken for an unspecified indication, start and stop date were not reported. There was no other vaccine in four weeks. The patient previously took propylene glycol, scopolamine and experienced drug allergy. The patient previously took the first dose of BNT162B2, administered in Arm Left on 16Mar2021 12:00 PM (at age of 19-year-old) (Lot number: EN6207) for COVID-19 immunisation. It was reported on 09Apr2021 12:00, the patient experienced chills and flu-like symptoms that developed into difficulty breathing/chest pain. Nerve pain in neck, severe rib pain, and spitting up blood constantly. The patient started spitting up blood about two days after the vaccine. The patient experienced severe pain and difficulty breathing on 12Apr2021. The patient received help from urgent care on 14Apr2021. On 14Apr2021, the patient was directed to receive a CT scan which revealed severe blood clotting in lungs. Rushed to ER where the patient was then admitted to the hospital overnight for observation and to receive blood thinners and pain medication. In the week since leaving the hospital the patient has experienced severe aches and pains all over her body and have continued to spit up blood. The events were reported resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event).The patient was hospitalized for the events for 2 days. Events treatment included: O2, Blood Thinners, Oxycodone, and Morphine. No COVID prior vaccination. COVID tested post vaccination on 14Apr2021, Nasal Swab, COVID-19 RNA - SARS Cov-2 test result was Negative . The outcome of events were recovering.</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1265810-1	60-64 years	Unknown	<p>sweating; felt cold/intense cold even in his bones; He was told by the professional health care that he had small clots in his blood; death cause: Medication; arm started to sore; Doctor identified he had DVT; her husband during that night was not able to sleep; He started having fever; This is a spontaneous report from a contactable consumer (patient's spouse). A 61-year-old male patient received bnt162b2 (BNT162B2), via an unspecified route of administration on 21Mar2021 09:00 (Batch/Lot number was not reported) as single dose f(at the age of 61-year-old) or COVID-19 immunisation. Medical history included dialysis, diabetes mellitus, known allergies: A7, Penicillin, Aspirin, Iodine, Povidone, Pepcid, dyes, iodine allergy. The patient's concomitant medications were not reported. The patient previously took Aspirin, povidone and pepcid ac and experienced drug hypersensitivity with all. Prior to vaccination, the patient was not diagnosed with COVID-19. The patient experienced death cause: medication on 18Apr2021, he was told by the professional health care that he had small clots in his blood in Mar2021, felt cold/intense cold even in his bones on 21Mar2021, sweating on 26Mar2021, her husband during that night was not able to sleep on 21Mar2021, he started having fever on 21Mar2021, arm started to sore and DVT on 29Mar2021. The patient was hospitalized for he had small clots in his blood, felt cold/intense cold even in his bones, sweating for 27 days. The event DVT was medically significant. The course of events was as follows: After getting the vaccine in 21Mar2021 her husband during that night was not able to sleep. He started having fever and felt cold. Days later he continued with the symptoms. On 26Mar2021 after vaccination he had dialysis same day in the afternoon. When arriving home the person notifies symptoms of intense cold even in his bones and then he started to sweat excessively on 26Mar2021 (Friday). The reporter decided to take her husband to the emergency room on 28Mar2021 (Sunday) where he had a general checkup. He was told by the professional health care that he had small clots in his blood. After some time he had health complications where they had suggested to amputate some of the limbs because of this, the reporter alleges those complications were due to the vaccine. On Monday 29Mar2021 same symptoms reappeared and he was admitted to Hospital. Had a blood test and notified to health professional that blood presents small clots. His arm started to sore severely after the sample. Doctor identified he had DVT. Doctor decided to proceed with various medications. Patient received treatment and he was injected: Percose, Morphine, Benadryl, Triphetarin for blood clot reduction. The patient underwent lab tests and procedures which included blood test: blood clot in Mar2021, Sars-cov-2 Nasal swab test: negative in Mar2021 post vaccination. The patient died on 18Apr2021. It was not reported if an autopsy was performed. The outcome of death cause: medication was fatal, of the other events was unknown. Information about the lot/batch number has been requested.; Reported Cause(s) of Death: death cause: Medication</p>
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COVID19 VACCINE	PFIZER\BIONTECH	1265973-1	65+ years	Unknown	<p>Blood clot in right lung; Sore left arm at injection site; Shortness of breath; This is a spontaneous report from a contactable consumer (patient). A 72-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose intramuscular, administered in the left upper arm on 03Feb2021 at 09:00 (batch/lot number: EL3248) as a single dose for COVID-19 immunisation (prevention). Medical history included rheumatoid arthritis from Dec2009 to an unknown date (takes daily pills for rheumatoid arthritis), squamous cell lung cancer early stage from Aug2018 to an unknown date, lung surgery to remove small portion of that and went on chemo in Aug2018, skin cancers prior to getting the vaccine, reading glasses (he needed prior to getting vaccine), blood pressure (abnormal) (takes blood pressure medication; takes daily pills). Family medical history was reported as none. Concomitant medications included nivolumab (OPDIVO) taken for squamous cell lung cancer early stage from 17Jan2019 to an unspecified stop date (getting it every 4 weeks for 2 years and 3 months; the bag was 480 ml); and unspecified blood pressure medication and rheumatoid arthritis medication. The patient experienced blood clot in right lung on 25Feb2021, sore left arm at injection site on 03Feb2021 and shortness of breath on Feb2021. The patient had the first Pfizer COVID vaccine on 03Feb2021 and second one on 01Mar2021. He did not really have any special events but then he had a CT scan on 23Feb2021, which was about 20 days after first shot. When he went in for doctor's meeting a couple of days later, they said he had a blood clot in right lung. He later stated he was not positive it was in the right lung. He told his doctor that he just got the shot, but they said they had not heard of any reports from Pfizer of people getting blood clots in their lungs after getting it. He thought about reporting then, but did not. He has no evidence that the blood clot in his lung was related to the vaccine. He was also a lung cancer patient and was on an immune therapy drug nivolumab from (name). He has been on it for over 2 years and started Jan2019. He was diagnosed with cancer back in Aug2018. It was squamous cell lung cancer early stage. He had lung surgery to remove small portion of that in Aug2018 and went on chemo. On 17Jan2019, he started on nivolumab immune therapy drug. Fortunately, it worked extremely well. He immediately started recovering and was feeling better. The last few CT scans indicated he had no sign of disease. It does not mean he was cured, but was healthy otherwise. The nivolumab spurred his immune system to eat the cancer cells. It stimulates your immune system. It has been a pretty successful drug and has been on the market for about 5-6 years. He and his wife both got shot on same date. The word on the street was that you should ask for Pfizer because it seems to have less side effects that people can get for vaccines. Pfizer's reputation has been known for having less common serious side effects. He had a sore arm and it went away about a day later. They prescribed rivaroxaban (XARELTO), a blood thinner, for his blood clot which he went on and got on a day or two later. He was hoping it was gone. He feels better. At the time, he did not know he had the blood clot. He visits his doctor for treatment for nivolumab every 4 weeks and every 4 months, they do a CT scan. At his last visit, he reported that he was still fine but lately experienced some shortness of breath. It was occasional and it comes and goes and was not all the time. He plays golf and noticed the shortness of breath during his game. He quit a couple of holes early and did not want to take any chances.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1266028-1	Unknown	Unknown	<p>portal vein thrombosis; thrombocytopenia; This is a spontaneous report from a contactable consumer (former colleague). A 6-decade-old (in her 50s) female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot and expiry were not reported), via an unspecified route of administration on 09Mar2021 as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient received the first dose of bnt162b2 around 09Mar2021 and was hospitalized 2 weeks later. It was reported that the patient experienced portal vein thrombosis and thrombocytopenia in 2021. The patient died in 2021 due to portal vein thrombosis and thrombocytopenia at a State hospital. No autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: Thrombocytopenia; portal vein thrombosis</p>

COVID19 VACCINE	PFIZER\BIONTECH	1266029-1	Unknown	Unknown	blood clot in my lung; This is a spontaneous report received from a contactable consumer (patient). A patient of unspecified age and gender received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number not reported), on unspecified date at single dose for COVID-19 immunization. The patient's medical history included he/she was not a smoker. The patient's concomitant medications were not reported. The patient previously received first dose of BNT162B2, on unspecified date at single dose for COVID-19 immunization. It was reported that patient had been diagnosed with a blood clot in his/her lung shortly after receiving his/her second dose of the COVID vaccine. He/she was not sure if they would be interested in what was going on in his/her case, but patient's doctor said it would be helpful to notify them and that they may be interested in this diagnosis. He/she had his/her legs and many other areas checked out (Ulta sounds etc), but there was no sign of clotting anywhere except for his/her lung so far. He/she was not a smoker and he/she had never had surgery or any major procedures. The outcome of the event was unknown. Information about lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1266035-1	Unknown	Unknown	have developed 2 massive blood clots; This is a spontaneous report from a contactable consumer (patient). A patient of unknown gender and age received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) in Feb2021 at single dose for COVID-19 immunisation. Medical history and concomitant medications were unknown. Historical vaccine included first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) in Jan2021 for COVID-19 immunisation. Since then, the patient had developed 2 massive blood clots. The patient did not have a history of blood clots. The outcome of the event was unknown. There was no doubt this was related. No follow-up attempts are needed; information about lot/batch number cannot be obtained.
COVID19 VACCINE	PFIZER\BIONTECH	1266038-1	Unknown	Unknown	Subsequently - a doctor discovered numerous blood clots in that leg; then a blood clot in one of her lungs; her left leg (she was inoculated on the left side) swelled up; it was painful; She is being treated but the lymphadenopathy has not subsided in her leg; she is now unable to walk without a cane; This is a spontaneous report from a contactable consumer. A 69-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number not reported) on an unspecified date in 2021 at single dose (inoculated on the left side) for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient received the vaccine few weeks ago, in 2021, and within 3 hours, she recounted her left leg (she was inoculated on the left side) swelled up dramatically it was painful. Subsequently a doctor discovered numerous blood clots in that leg, then a blood clot in one of her lungs. She is being treated but the lymphadenopathy has not subsided in her leg and she was now unable to walk without a cane. The outcome of lymphadenopathy and unable to walk without a cane events was not recovered; outcome of the other events was unknown. Reporter asked if there were reports of blood clots that have been validated as a result of the Pfizer shot. Information on the lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1266051-1	65+ years	Unknown	blood clot; lymphadenopathy; unable to walk without a cane; her left leg swelled up dramatically; painful leg; This is a spontaneous report from a contactable consumer. A 69-year-old female patient received her first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on an unspecified date (at the age of 69-years-old) as single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. It was reported that patient received Pfizer shot a few weeks before reporting. Within 3 hours her left leg (she was inoculated on the left side) swelled up dramatically -- it was painful. Subsequently - a doctor discovered numerous blood clots in that leg; then a blood clot in one of her lungs. She was being treated but the lymphadenopathy has not subsided in her leg and she was now unable to walk without a cane. Lymphadenopathy was not resolved; the outcome of the other events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

COVID19 VACCINE	PFIZER\BIONTECH	1266057-1	60-64 years	Unknown	<p>strokes signs; Two blood clots in the veins in legs; This is a spontaneous report from a contactable consumer. A 64-year-old female consumer (patient) reported that she received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number EN6199/EN6207 (as reported)) intramuscular into the left arm on 10Mar2021 (at the age of 64-years-old) at single dose for COVID-19 immunization. She received the second dose of BNT162B2 dose on 31Mar2021 (lot number unknown). Medical history included high blood pressure and GERD. Concomitant drugs included Toprol 25mg, oral , twice a day for blood pressure stated "in Feb some time she don't know" and Protonix 40mg, oral twice a day for years for GERD. The consumer reported that 'she got her first vaccine and she has had the strokes signs". Further she reported she got her first vaccine dose, then she had leg pain, she went to see the doctor and ordered a doppler. She was put on blood thinners and three days later she got two blood clots in the veins of her legs, right. On 20Mar2021, her leg pain went pretty severe since I had the blood clot, when I got the second shot, it was still there. On 27Mar2021 she started treatment receiving Eliquis 5mg, twice a day for the blood clot and she did take a Physical therapy. When she got the second vaccine dose on 31Mar2021 she was on blood thinners. At the time of reporting the outcome of the event was reported as 'hasn't gotten better, it's the same not better not worse.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1266078-1	Unknown	Unknown	<p>pulmonary embolism; short of breath; This is a spontaneous report from a non-contactable consumer via Pfizer sales representative. A 63-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 2 via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient died of pulmonary embolism 2 days after 2nd vaccine dose. She had been short of breath the day after the shot, called the pharmacy where she'd received it, and they told her to go to ER. The reporter thought that she did not go to the ER, and then later died at home. It was unknown if an autopsy was performed. Outcome of the event short of breath at the time of death was unknown. No follow-up attempts are possible; Information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: pulmonary embolism</p>
COVID19 VACCINE	PFIZER\BIONTECH	1269519-1	65+ years	Unknown	<p>Large DVT in leg femoral popliteal; This is a spontaneous report from a contactable consumer, the patient. A 74-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN) via an unspecified route of administration on an unspecified date (at the age of 74-years-old) as a single dose for COVID-19 immunisation. The patient medical history was none. Prior to vaccination, the patient was not diagnosed with COVID-19. There were no concomitant medications. The patient previously received the first dose of BNT162b2 on 18Jan2021 at 12:00 (Lot Number: Unknown) for COVID-19 immunisation. The patient had not received any other vaccines within 4 weeks prior to the COVID-19 vaccine. The patient experienced large DVT in leg femoral popliteal without other cause on 24Mar2021, diagnosed 3-4 weeks after the 2nd vaccine. The patient underwent lab tests and procedures which included PCR COVID test on 24Mar2021 (post vaccination), which was negative. Therapeutic measures included rivaroxaban (XARELTO) as a result of large DVT in leg femoral popliteal (deep vein thrombosis). The patient was recovering from the event, large DVT in leg femoral popliteal. No follow up attempts are possible; Information about Lot and batch number could not be obtained.</p>



COVID19 VACCINE	PFIZER\BIONTECH	1278551-1	Unknown	Unknown	short of breath; chest pain; she had a blood clot and was diagnosed with a blood clot/diagnosed with DVT; Red splotches on leg; This is a spontaneous report from a contactable Nurse. A 62-year-old female patient received first dose of BNT162B2 (BNT162B2), via an unspecified route of administration, administered in Arm Right on an unspecified date (Batch/Lot Number: EW0150) as SINGLE DOSE for covid-19 immunization. Medical history included she had a blood clot after surgery 100 pounds ago, around 18 years ago, she had the heart attack at age 41 and thrombophlebitis from an unknown date and unknown if ongoing. Concomitant medications included aspirin [acetylsalicylic acid] (ASPIRIN [ACETYLSALICYLIC ACID]) taken for cardiac disorder from an unspecified start date and ongoing. The patient experienced she had a blood clot and was diagnosed with a blood clot/diagnosed with DVT on 10Apr2021 and red splotches on leg on 09Apr2021. She states she got the vaccine on Thursday 08Apr2021. She confirms that the painful red splotches showed up on 09Apr2021. The blood Clot was diagnosed on the 10Apr2021. She states that the doctors put her on Lovenox. She states that it is only significant if she gets short of breath and/or has chest pain. If it travels then it is significant. She states that her doctor said she had a good sized clot, but she didn't ask specifics. Outcome of the event was not recovered.; Sender's Comments: On the basis of the available information, the reported event DVT would seem most likely related to underlying medical conditions which is not related to BNT162B2.
COVID19 VACCINE	PFIZER\BIONTECH	1278972-1	Unknown	Unknown	find out if his side effects are normal or if he maybe has a ""blood clot.""; the shoulder and neck on the side where he received his injection are swollen and painful; the shoulder and neck on the side where he received his injection are swollen and painful; the shoulder and neck on the side where he received his injection are swollen and painful; across his collar bone is painful; my lips, nodes and top of my right my trap area is swollen; my lips, nodes and top of my right my trap area is swollen; I was told you might swollen on arm where shot went it or under your armpit not on top on my neck; This is a spontaneous report from a contactable consumer (patient). A male patient of an unspecified age received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 17Apr2021 (lot number and expiry date not reported) as single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. Historical vaccine included first dose of bnt162b2 on an unspecified date for COVID-19 immunization. The patient stated that he received his second dose of the Pfizer COVID-19 vaccine on Saturday 17Apr2021. He stated that he called Pfizer yesterday, Sunday 18Apr2021 and reported his side effects, but was not able to have his questions answered. He was calling back to find out if his side effects were normal or if he maybe had a ""blood clot."" The patient stated that the shoulder and neck on the side where he received his injection were swollen and painful. The patient stated that across his collar bone was painful. He stated that the swelling and pain had improved slightly since yesterday. He stated that other than these side effects he feels great. He added, ""I just got my second shot yesterday. No symptoms showed up except my lips nodes and top of my, right my trap area is swollen. So I want to make sure, is that normal? Because I was told you might swollen on arm where shot went it or under your armpit not on top on my neck."" Clinical outcome of blood clot was unknown, while for the other events was recovering. Information on the lot/batch number has been requested.""
COVID19 VACCINE	PFIZER\BIONTECH	1279051-1	Unknown	Unknown	DVTs in both legs; Femoral artery clotted from my thigh to my ankle; This is a spontaneous report from a Pfizer-sponsored program, PFIZER RXPATHWAYS. A contactable consumer (patient) reported that a male patient of an unspecified age received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number and expiration date were not reported) as a single dose, with route of administration and therapy date unspecified, for COVID-19 immunization. The patient's medical history was not reported. Concomitant medication included apixaban (ELIQUIS). The patient had previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number and expiration date were not reported) on an unspecified date for COVID-19 immunization. On an unspecified date, the patient had deep vein thrombosis (DVTs) in both legs; and femoral artery had clotted from the thigh to the ankle. The events were assessed as serious (medically significant). The outcome of the events was unknown. Information about batch/Lot number has been requested.

COVID19 VACCINE	PFIZER\BIONTECH	1279063-1	65+ years	Unknown	Thrombocytopenia; He had clot in the legs and in the lungs; He had clot in the legs and in the lungs; Low platelet count; This is a spontaneous report from a contactable Other-HCP. A 67-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation (Age at vaccination: 67 years). Medical history included diabetes. Concomitant medication(s) included atorvastatin (LIPITOR [ATORVASTATIN]); colecalciferol (VITAMIN D [COLECALCIFEROL]); lisinopril; insulin taken for diabetes mellitus. The patient experienced thrombocytopenia, he had clot in the legs and in the lungs and have a low platelet count on an unspecified date. The patient was hospitalized for the events on an unspecified date. The patient underwent lab tests and procedures which included CBC: unknown result on 08Apr2021, Heparin associate antibody: unknown result, comprehensive metabolic panel (CMP): unknown result and platelet count: low on an unspecified date. Therapeutic measures were taken as a result of thrombosis included Heparin drip and Argatroban. Outcome of the events was unknown. Information about lot/batch number has been requested.; Sender's Comments: The reported events are considered unrelated to BNT162B2 vaccine, being rather intercurrent occurrences. Clots in the legs and in the lungs were likely favored by the mentioned diabetes and by a possible hyperlipidemia (the patient was taking atorvastatin) in a setting of possible arterial hypertension (the patient was taking lisinopril). The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1279190-1	50-59 years	Unknown	two blood clots in his leg; This is a spontaneous report from a contactable consumer reporting on behalf of the patient. A 57-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose on 08Feb2021 (Lot Number: EM9810, unknown expiration) and second dose on 02Mar2021 (Lot Number: ENU202, unknown expiration; pending clarification), both received at the age of 57 years old via unspecified route of administration as a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The reporter called to report that the patient had a Pfizer vaccine, received second COVID vaccine on 02Mar2021, and couples of weeks ago, a week longer that the patient was diagnosed with two blood clots in his leg. The patient got both of COVID-19 vaccine. Outcome of the event was unknown. Information on the lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1279205-1	Unknown	Unknown	I got a blood clot in my varicose vein in my left leg; This is a spontaneous report from a contactable consumer(patient). A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number was not reported), on an unspecified date at single dose for covid-19 immunisation. The patient medical history included varicose vein in the left leg. Concomitant medications were not reported. On an unspecified date in Apr2021, the patient developed a blood clot in the varicose vein in the left leg. Patient clarified that after talking to the doctor patient thought may had the adverse reaction to the first vaccine. Patient was supposed to get Pfizer Vaccine at the day of reporting but when talk to doctor and the urgent care where was supposed to be getting it, rescheduled it for 04May2021 because 3 days before (in Apr2021) patient got a blood clot in varicose vein in left leg so, they didn't want to go and get the vaccine and rescheduled it for 04May2021. Patient asked if he/she should even get the second vaccine.The final outcome of the event was unknown. Information on the lot/batch number has been requested

COVID19 VACCINE	PFIZER\BIONTECH	1284764-1	Unknown	Unknown	<p>with right leg, severe pain and had DVT diagnosed/ diagnose with DVT (deep vein blood clot) in my leg; This is a spontaneous report from a contactable consumer (patient). A female patient (Age: 60; Unit: Unspecified) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, administered in left arm on 17Mar2021 (Batch/Lot number was not reported) as single dose for COVID-19 immunisation. Medical history included COVID-19 from 02Oct2020 to an unknown date. Concomitant medications were not reported. The patient experienced with right leg, severe pain and had dvt diagnosed/ diagnose with dvt (deep vein blood clot) in my leg on an unspecified date in 2021 with outcome of unknown. Patient states she had COVID-19 on 02Oct2020. She received her first Pfizer vaccine dose in her left arm on 17Mar2021. On 01Apr2021, she went to the hospital ED with right leg, severe pain and had DVT diagnosed. She was sent home from the ED with Xarelto. On 07Apr2021, 2nd vaccine dose received by patient. Consumer stated, ""I called the health department and I just wanted you to record that I called you guys back on 17Mar I've had my first COVID shot and then 01Apr, I went to the hospital (further details for the hospitalization not available hence not checked as seriousness criteria) and diagnose with DVT (deep vein blood clot) in my leg. I just felt, I just know that what going on right now with Johnson and Johnson but I am just trying to kind of understand that 2 weeks to the day that I had my first COVID shot I came down with the blood clot in my leg. So I just wanted to see if that's anything that I need to concerned, it's very painful, fortunately I have been able to work from home but it's very painful and I did get my second round because level one I need to think about it. So, with everything going on. I never had blood clot now before that I have now."" Information on the lot/batch number has been requested.""</p>
COVID19 VACCINE	PFIZER\BIONTECH	1284805-1	40-49 years	Unknown	<p>more than usual vaginal bleeding/with very dark blood with clots.; menstrual cramps; sharp pelvic pain; more than usual vaginal bleeding; more than usual vaginal bleeding; This is a spontaneous report from a contactable consumer (patient). A 40-year-old female non-pregnant patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 05Apr2021 10:30 (Batch/Lot Number: ER8734) as single dose for covid-19 immunisation. Facility type Vaccine: Other. Medical history included known allergies: Sulfa and Folate deficiency. The patient's concomitant medications were not reported. The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EN6206) on 15Mar2021 10:30 AM in left arm for covid-19 immunisation and experienced vaginal bleeding/blood clots at mid-cycle on 15Mar2021 08:00 PM. If other vaccine in four weeks: No. Other medications in two weeks: No. If Covid prior vaccination: No. If Covid tested post vaccination: No. The patient experienced more than usual vaginal bleeding/with very dark blood with clots, menstrual cramps, sharp pelvic pain, all on Apr2021 with outcome of not recovered. Clinical course: After the first dose, the patient had vaginal bleeding/blood clots at mid-cycle. The same day after the 2nd dose, she started feeling menstrual cramps and sharp pelvic pain. After taking paracetamol (TYLENOL) and feeling a bit of relief, she stood up and started having more than usual vaginal bleeding at the level that it reached the floor as if it was a hemorrhage with very dark blood with clots. This lasted for 1 minute. This lasted for 5 days and 7 days later, she started bleeding again with dark blood clots for a period of 3 days. The events resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. No treatment received for events more than usual vaginal bleeding/with very dark blood with clots.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1288390-1	Unknown	Unknown	<p>passing blood clots/having a total of 4 of them she has passed/noticing one when she went to the bathroom to urinate; she went into the bathroom and wiped, without actually going to the bathroom, she noticed the blood clot(s); felt like she needed to go to the bathroom/felt weird like something needed to come out; headache; dizziness; hot and cold sweats; This is a spontaneous report from a contactable consumer (who is also the patient). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date not reported), via an unspecified route of administration, on 16Apr2021, as single dose, for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. In Apr2021, after the first vaccination, the patient experienced ""some of the usual side effects"" described further as headache, dizziness, and hot and cold sweats. On 18Apr2021, 2 days after the first vaccination, the patient experienced passing blood clots having a total of 4 of them she has passed. She reported noticing one when she went to the bathroom to urinate. For the other blood clots, she reported it felt like she needed to go to the bathroom further described as ""felt weird like something needed to come out."" When she went into the bathroom and wiped, without actually going to the bathroom, she noticed the blood clot(s). The outcome of the events was unknown. No follow-up attempts are needed; information about lot/batch number cannot be obtained.""</p>
COVID19 VACCINE	PFIZER\BIONTECH	1288420-1	Unknown	Unknown	<p>clots; I received the pfizer vaccine and within 2 weeks had bruising; low platelets; This is a spontaneous report from a contactable consumer, the patient. This patient of unspecified age and gender received BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Lot Number: UNKNOWN) via unspecified route on unspecified date as a single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient reported that he/she received the vaccine and within 2 weeks had bruising, low platelets and clots (unspecified date). Lab data included platelets: low on unspecified date. The clinical outcomes of bruising, low platelets and clots were unknown. The lot number for the vaccine, BNT162b2, was not provided and will be requested during follow up.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1288423-1	Unknown	Unknown	<p>Blood clots in her nose; Nose bleed; her arms are both numb on her; Couldn't move them; She feels lethargic; This is a spontaneous report from a contactable consumer (patient herself) via a medical information team. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection), via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that, enquired have people died from the vaccine or not. Enquired what do you know about the news in the media about reports of death in nursing home elderly patients. Response: Pfizer and BioNTech are aware of reported deaths following administration of Pfizer-BioNTech COVID-19 vaccine . We are working with the (withheld) to gather all the relevant information. (Withheld) Authorities have prioritized the immunization of residents in Nursing Homes, most of whom are very elderly with underlying medical conditions and some which are terminally ill. (Withheld) confirm the number of incidents so far was not alarming, and in line with expectations. All reported deaths would be thoroughly evaluated by (Withheld) to determine if these incidents are related to the vaccine. (Withheld) Health Authorities have now changed its recommendation in relation to vaccination of the terminally ill (Clinical Frailty Scale 8 or higher). Our immediate thoughts are with the bereaved families. The Global Advisory Committee on Vaccine Safety (GACVS) COVID-19 Vaccine Safety subcommittee met virtually on Tuesday, 19Jan2021, to review available information and data on deaths reported in frail, elderly individuals who had received the Pfizer BioNTech COVID-19 mRNA vaccine, BNT162b2 (hereafter, BNT162b2). Experts invited from the (Withheld) and the (Withheld) provided an overview of deaths reported in (Withheld) and in the WHO global database (VigiBase) following vaccination with BNT162b2." Based on a careful scientific review of the information made available, the subcommittee came to the following conclusions: The current reports do not suggest any unexpected or untoward increase in fatalities in frail, elderly individuals or any unusual characteristics of adverse events following administration of BNT162b2. Reports are in line with the expected, all-cause mortality rates and causes of death in the sub-population of frail, elderly individuals, and the available information does not confirm a contributory role for the vaccine in the reported fatal events. In view of this, the committee considers that the benefit-risk balance of BNT162b2 remains favourable in the elderly, and does not suggest any revision, at present, to the recommendations around the safety of this vaccine." Enquired what was the efficacy after one dose. Caller had a terrible experience after her first dose of the Pfizer BioNTech COVID19 vaccine. She had blood clots in her nose, every time she blew her nose, blood clots would come out. She never had a nose bleed before. She also added that her arms are both numb on her. She couldn't move them, she feels lethargic. She's supposed to get her second dose next Friday. Enquired do we have any information regarding blood clots or not. Caller was upset and disconnected the call before some of the answers were given. Caller also asked the following questions: Has there been deaths reported from the vaccine or not, what was the efficacy after 1 dose, any guidance on getting the second dose after having side effects after the first dose. Response: Proposed response : CONS-Blood clots. Caller said ""this was ridiculous""</p>
COVID19 VACCINE	PFIZER\BIONTECH	1288432-1	Unknown	Unknown	<p>My grandma got a PFIZER COVID VACCINE and has now experienced a blood clot that caused a stroke.; My grandma got a PFIZER COVID VACCINE and has now experienced a blood clot that caused a stroke.; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Lot number unknown), via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunization. The patient's medical history was not reported. The patient's concomitant medications were not reported. The reporter stated that ""my grandma got a pfizer covid vaccine and has now experienced a blood clot that caused a stroke."" The patient experienced a cerebrovascular accident on an unspecified date with outcome of unknown and thrombosis on an unspecified date with outcome of unknown. No further information was provided. Information on the Lot/Batch number has been requested.""</p>

COVID19 VACCINE	PFIZER\BIONTECH	1288442-1	Unknown	Unknown	<p>minor blood clot on his leg; This is a spontaneous report from a Pfizer-sponsored program received from a contactable consumer (patient). A male patient of unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number not reported), on 03Apr2021 at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that patient had the first dose on 03Apr2021 and he was scheduled on Saturday 24Apr2021 to get the second dose of the vaccine. However, the patient had a minor blood clot on his leg, and he was taking blood thinners. Patient asked if it was okay to get the vaccine while talking to the blood thinners (as reported). The outcome of the event was unknown. Information about lot/batch number has been requested.</p>
COVID19 VACCINE	PFIZER\BIONTECH	1291138-1	Unknown	Unknown	<p>The pain I feel, Could be due to a blood clot?; pain on my arm; felt numbness in my arm; now I feel it on the inside, like if it was in the bone.; This is a spontaneous report from a contactable consumer (patient). A 42-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration in the arm on an unspecified date (Batch/Lot number was not reported) as a single dose for COVID-19 immunization. Medical history was not reported. Concomitant medication included paracetamol (TYLENOL) taken for an unspecified indication, start and stop date were not reported. The patient received the Pfizer Covid 19 vaccine on Friday, since then she felt pain on her arm, it got stronger in the afternoon, she couldn't lift anything or move that arm. On Saturday, the pain diminished. On the day of the report, the patient still feel pain, but now is like an internal ache, like if it is in the bone. She had trouble getting dressed, specially putting on t-shirts, when she goes to sleep, she cannot lay on that arm. It was reportedly very painful, and she was feeling as if it has moved to the other arm. On the day of the report, she applied heat on her arm and took Tylenol on Friday and Saturday. On Friday, she couldn't do anything, she felt numbness in her arm. Initially the pain was external, now she feels it on the inside, like if it was in the bone. The patient also asked if the pain she feel could be due to a blood clot. The event pain on my arm resolved on an unknown date in 2021, while the outcome of the rest of the events was unknown. Information about lot/batch number has been requested.</p>

COVID19 VACCINE	PFIZER\BIONTECH	1294675-1	30-39 years	Unknown	<p>blood clot; anemia; knee down felt tingly/like her legs were falling asleep; knee down felt tingly/like her legs were falling asleep; could not sleep; She was feeling uncomfortable constantly/she did not feel well; Shortness of breath; Her arm started hurting/was just at the injection site; This is a spontaneous report from a contactable consumer. This consumer (patient) reported for herself that a 36-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EP7533) at the age of 36-years, via an unspecified route of administration in left arm on 04Apr2021 12:15 at single dose for COVID-19 immunisation. Medical history included had a pregnancy (a while ago, not ongoing). No other products. The patient stated that she experienced shortness of breath on 08Apr2021 (4 days after receiving the first dose), it got so severe on day 7 that she went to the ER on 11Apr2021. She started getting progressively more shortness of breath. Twice, she called the nurse line for her doctor and was advised to go to the emergency room. Added she could not catch her breath, and it was worse at night, could not sleep, so she went to the emergency room, she was in emergency room for 2 and a half hours and then went home. She wanted to know if the second dose could cause issues or if she should get it, added that the paperwork said that people should not get the vaccine if they received an adverse reaction to the first dose or any vaccination. She did not know if this was normal for it to get progressively worse and 2 to 14 days later. Patient wanted to know if the shortness of breath was something that can get worse, if this was a reaction to the vaccine even though it happened so many days later. Patient added it was the only thing she could think of and that her heart rate, oxygen levels, and everything was good minus she felt like she could not catch her breath. The doctor in the ER gave her anti-anxiety medicine, something with an L, but the doctor gave her that and it really seemed to help. It was kind of like, she did not know, it made her feel calm enough to fall asleep. Caller added that she has that and an salbutamol (ALBUTEROL) inhaler. She was not sure whether progressively worsening shortness of breath had gotten any better or was still going on, added that yesterday was the day she did not need either treatment medication. The day before, she took just the anxiety medicine and not the albuterol. Yesterday, she took none. During the day on 11Apr2021 (Sunday), she had called because she was feeling uncomfortable constantly. She has two children and all day she did not feel well. She told her husband she did not feel well at all. Sunday when she went to lay down, she could not sleep. Patient reported that as her shortness of breath subsided, her arm started hurting again, thought this began on 19Apr2021 and was not sure, it went away completely and was just at the injection site, probably lasting half a day or so and then it went away, clarified as left arm, same as injection. Caller added that 15Apr2021 was after the ER visit, was that she was standing up doing things and from her knee down felt tingly. Stated that knee down felt tingly on 15Apr2021, which was after her ER visit occurred, she was standing up and doing things. She had not been doing things for long periods but her knee down felt tingly. Added not like numb, but like her legs were falling asleep. She was preparing dinner and moving around and felt tingling in both legs. This probably lasted about three hours. She just kind of took it easy and it started to subside and then it was gone. While mentioned investigations, patient stated the ER did an EKG, where they put stickers and monitor</p>
COVID19 VACCINE	PFIZER\BIONTECH	1294714-1	Unknown	Unknown	<p>Cerebral venous sinus thrombosis; This is a spontaneous report from a contactable consumer, the patient. This 69-year-old male patient the second dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EN5318; Expiration Date: 31May2021), via an unspecified route of administration in the left arm on an unspecified date as single dose for COVID-19 immunization. The patient's medical history was not reported. There were no concomitant medications. The patient previously took the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: Unknown) via an unspecified route of administration on an unspecified date as single dose for COVID-19 immunization. On 08Mar2021, the patient experienced cerebral venous sinus thrombosis and treated with PRADAXA. The patient underwent multiple ""over 100"" unspecified lab tests in the hospital with unknown results. The patient was hospitalized for cerebral venous sinus thrombosis from 26Mar2021 to 28Mar2021. The clinical outcome of cerebral venous sinus thrombosis was improved/resolving.""</p>
COVID19 VACCINE	UNKNOWN MANUFACTURER	1012226-1	50-59 years	Unknown	<p>Member has reported was hospitalited for Pulmonary Embolism that happened, COVID-19. States COVID-19 vaccination 02FEB2021, physician ordered to not take therapy until the 2nd COVID-19 vaccination on 23FEB2021. Also, experiencing hands &amp; feet are swollen. Event Ongoing.</p>

COVID19 VACCINE	UNKNOWN MANUFACTURER	1276503-1	Unknown	Unknown	LEG PAIN DIAGNOSED AS BLOOD CLOT; HEADACHE; MILD FEVER; This spontaneous report received from a patient concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, and batch number: 201A21A expiry: unknown) dose was not reported, 1 in total administered on 09-APR-2021 to left arm for prophylactic vaccination. No concomitant medications were reported. On an unspecified date, in APR-2021, the patient experienced mild fever (99 degrees fahrenheit), headache and leg pain diagnosed as blood clot (leg pain) on 21-APR-2021. On an unspecified date in APR-2021, laboratory data included: Body temperature (NR: not provided) 99 F, and Diagnostic ultrasound (NR: not provided) unknown. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the leg pain diagnosed as blood clot, headache and mild fever was not reported. This report was serious (Other Medically Important Condition).; Sender's Comments: V0:2021045225-covid-19 vaccine ad26.cov2.s-Leg pain diagnosed as blood clot. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).
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Dataset: The Vaccine Adverse Event Reporting System (VAERS)

Query Parameters:

State / Territory: The United States/Territories/Unknown

Symptoms: AIR EMBOLISM; ANAPHYLACTOID SYNDROME OF PREGNANCY; AORTIC THROMBOSIS; ARTERIAL THROMBOSIS; ARTERIAL THROMBOSIS LIMB; ATRIAL THROMBOSIS; AXILLARY VEIN THROMBOSIS; BASILAR ARTERY THROMBOSIS; BRACHIOCEPHALIC VEIN THROMBOSIS; CAROTID ARTERY THROMBOSIS; CAVERNOUS SINUS THROMBOSIS; CEREBELLAR EMBOLISM; CEREBRAL ARTERY EMBOLISM; CEREBRAL ARTERY THROMBOSIS; CEREBRAL THROMBOSIS; CEREBRAL VENOUS SINUS THROMBOSIS; CEREBRAL VENOUS THROMBOSIS; CORONARY ARTERY EMBOLISM; CORONARY ARTERY THROMBOSIS; DEEP VEIN THROMBOSIS; EMBOLISM; EMBOLISM ARTERIAL; EMBOLISM VENOUS; FEMORAL ARTERY EMBOLISM; HAEMORRHAGE URINARY TRACT; HEPATIC VEIN THROMBOSIS; ILIAC ARTERY THROMBOSIS; INJECTION SITE THROMBOSIS; INTRACARDIAC THROMBUS; INTRACRANIAL VENOUS SINUS THROMBOSIS; JUGULAR VEIN THROMBOSIS; MESENTERIC VEIN THROMBOSIS; MICROEMBOLISM; OPHTHALMIC ARTERY THROMBOSIS; OPHTHALMIC VEIN THROMBOSIS; PELVIC VENOUS THROMBOSIS; PERIPHERAL ARTERY THROMBOSIS; PERIPHERAL EMBOLISM; PORTAL VEIN THROMBOSIS; PULMONARY ARTERY THROMBOSIS; PULMONARY EMBOLISM; PULMONARY THROMBOSIS; RENAL EMBOLISM; RENAL VEIN EMBOLISM; RETINAL ARTERY EMBOLISM; RETINAL ARTERY THROMBOSIS; RETINAL VASCULAR THROMBOSIS; RETINAL VEIN THROMBOSIS; SPLENIC VEIN THROMBOSIS; SUBCLAVIAN VEIN THROMBOSIS; SUPERIOR SAGITTAL SINUS THROMBOSIS; THROMBOPHLEBITIS SUPERFICIAL; THROMBOSIS; THROMBOSIS IN DEVICE; TRANSVERSE SINUS THROMBOSIS; TRUNCUS COELIACUS THROMBOSIS; UMBILICAL CORD THROMBOSIS; VENA CAVA EMBOLISM; VENA CAVA THROMBOSIS; VENOUS THROMBOSIS; VENOUS THROMBOSIS LIMB

Vaccine Products: COVID19 VACCINE (COVID19)

VAERS ID: All

Group By: Vaccine Type; Vaccine Manufacturer; VAERS ID; Age; Onset Interval

Show Totals: False

Show Zero Values: Disabled

Help: See <http://wonder.cdc.gov/wonder/help/vaers.html> for more information.

Query Date: May 17, 2021 7:26:31 PM

Suggested Citation: Accessed at <http://wonder.cdc.gov/vaers.html> on May 17, 2021 7:26:31 PM

Messages:

1. The full results are too long to be displayed, only non-zero rows are available.
2. VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
3. **These results are for 2,536 total events.**
4. When grouped by VAERS ID, results initially don't show Events Reported, Percent, or totals. Use Quick or More Options to restore them, if you wish.
5. Click on a VAERS ID to see a report containing detailed information for the event.

Footnotes:

1. Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

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Caveats:

1. VAERS accepts reports of adverse events and reactions that occur following vaccination. Healthcare providers, vaccine manufacturers, and the public can submit reports to VAERS. While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. The reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Most reports to VAERS are voluntary, which means they are subject to biases. This creates specific limitations on how the data can be used scientifically. Data from VAERS reports should always be interpreted with these limitations in mind. The strengths of VAERS are that it is national in scope and can quickly provide an early warning of a safety problem with a vaccine. As part of CDC and FDA's multi-system approach to post-licensure vaccine safety monitoring, VAERS is designed to rapidly detect unusual or unexpected patterns of adverse events, also known as "safety signals." If a safety signal is found in VAERS, further studies can be done in safety systems such as the CDC's Vaccine Safety Datalink (VSD) or the Clinical Immunization Safety Assessment (CISA) project. These systems do not have the same limitations as VAERS, and can better assess health risks and possible connections between adverse events and a vaccine.

Key considerations and limitations of VAERS data:

- Vaccine providers are encouraged to report any clinically significant health problem following vaccination to VAERS, whether or not they believe the vaccine was the cause.
- Reports may include incomplete, inaccurate, coincidental and unverified information.
- The number of reports alone cannot be interpreted or used to reach conclusions about the existence, severity, frequency, or rates of problems associated with vaccines.
- VAERS data are limited to vaccine adverse event reports received between 1990 and the most recent date for which data are available.
- VAERS data do not represent all known safety information for a vaccine and should be interpreted in the context of other scientific information.

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3. Some items may have more than 1 occurrence in any single event report, such as Symptoms, Vaccine Products, Manufacturers, and Event Categories. If data are grouped by any of these items, then the number in the Events Reported column may exceed the total number of unique events. If percentages are shown, then the associated percentage of total unique event reports will exceed 100% in such cases. For example, the number of Symptoms mentioned is likely to exceed the number of events reported, because many reports include more than 1 Symptom. When more than 1 Symptom occurs in a single report, then the percentage of Symptoms to unique events is more than 100%. More information: <http://wonder.cdc.gov/wonder/help/vaers.html#Suppress>.

4. Data contains VAERS reports processed as of 5/7/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. More information: <http://wonder.cdc.gov/wonder/help/vaers.html#Reporting>.

5. For more information on how many persons have been vaccinated in the US for COVID19 to date, see <https://covid.cdc.gov/covid-data-tracker/#vaccinations/>