COVID Vaccine VAERS Reports for Blood Clots / Thrombosis / Embolism - April 10, 2021

Notes	Vaccine Type	Vaccine Manufacturer	VAERS ID	Age	Onset Interval	Adverse Event Description
	COVID19 VACCINE	JANSSEN	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 serve 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 side, 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 immediate 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 Pomologist 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	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 Ophthamologist 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 breath; 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	Blg 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 is 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	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	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-Feb2021, 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	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	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	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 a78, year, old, female patient who developed a blood clot in the left forearm. The patient's medical history included hypertension, hiigh 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 apxaban (One 5 milligram AM and PM) and Asprin. 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 apxaban two tablets of 5 milligrams AM and PM and to discontinue the Asprin 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 Sonagram and discovered a DVT and later a Pulmonary Embolism in my right lower lung. I am now on Eliquis.
COVID19 VACCINE	MODERNA	1107202-1	Unknown	0 days	Migraines have became 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 became 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 became 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 became 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	1127468-1	65+ years	0 days	Severe lethargy after receiving the shot. Constant sleepiness and malaise, nausea, confusion, loss of appetite, dizziness, Blood vessels/clots formed in her eyes. Acute renal failure and eventually death on March 18, 2021.
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	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 vericose vein. I sought tx at an ER on 12/26 to ensure it was not a blod clot. I followed up with my family dr on 1/4/2021 (When her office reopend) and was diagnosed with Superficial Thrombophlebitis. The knots remain in my leg. The redness has mostly gone away. My PCP felt as I recenlty had covid, the vaccine likely flared up the inflamation 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	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 sycnope (conflicting documentation) with humeral fracture after recieving 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	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 approximatly 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 desolve the blood clot on my lung. Doctor suggested I report Pulmonary Embolism occuring same day as my first vaccine shot. Do not know if shot caused Pulmonary Embolism or just a coinsidence. 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	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.""
COVID19 VACCINE	PFIZER\BIONTECH	1062452-1	40-49 years	0 days	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.

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	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.""

COVID19 VACCINE	PFIZER\BIONTECH	1070763-1	65+ years	0 days	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.
COVID19 VACCINE	PFIZER\BIONTECH	1072556-1	65+ years	0 days	right leg showed blood clot in lower back of leg from ankle to knee; right leg calf was red swollen and throbbed; 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 throbbed 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.

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	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	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	1103636-1	65+ years	0 days	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.
COVID19 VACCINE	PFIZER\BIONTECH	1113713-1	65+ years	0 days	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.

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	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 catherization 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	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	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	0974753-1	65+ years	1 day	Experienced shortness of breath upon minimal exertion 24 hours after having receieved 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 rbcs Urine lytes 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 clotting. 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	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	1033966-1	65+ years	1 day	post vaccine fever, hypoxia, pulmonary embolisms

COVID19 VACCINE	MODERNA	1038250-1	65+ years	1 day	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 Êpossibly related'
COVID19 VACCINE	MODERNA	1045548-1	65+ years	1 day	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.
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 x 3 days. also complains of intemrittent 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 ha 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	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 flulike 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	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	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	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	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	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 tocilzumab, 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	PFIZER\BIONTECH	0916795-1	40-49 years	1 day	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 clementine. 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
COVID19 VACCINE	PFIZER\BIONTECH	0923031-1	30-39 years	1 day	Worsening arm pain after injection that eventually resulted in my being diagnosed with a blood clot in the arm that I recevied the injection on

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	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	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 opthalmic 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 or 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	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	1075308-1	60-64 years	1 day	still have sore muscles in my shoulders; still feeling bad with all the above symtoms; 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 septra 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 Practicioner 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	1105251-1	40-49 years	1 day	n/v, chills, SOB, pulmonary embolism, pericardial effusion
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	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	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	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 ""signficant conditions contributing to death after cardiac arrest; ASCVD"".””
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 tiered. 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	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	1126609-1	60-64 years	2 days	CARDIOPULMONARY ARREST 2 DAYS AFTER RECIEVING SECOND MODERNA DOSE
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, 02 80%, temperature unable to read temporally 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. 02 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	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	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	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 though 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 Xeralto. 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	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	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	1140696-1	65+ years	2 days	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, colecalciferol (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
COVID19 VACCINE	JANSSEN	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	JANSSEN	1117313-1	50-59 years	3 days	Blood clot perpendicular to injection site
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	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 antibiotic s and a heparin drip

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	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	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	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 occured 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 occured 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
COVID19 VACCINE	PFIZER\BIONTECH	0992810-1	65+ years	3 days	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.
COVID19 VACCINE	PFIZER\BIONTECH	1011807-1	65+ years	3 days	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.
COVID19 VACCINE	PFIZER\BIONTECH	1015212-1	18-29 years	3 days	Deep Venous Thrombosis of Right Axillary and Subclavian vein. Treated with IV Heparin Drip.
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	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	1102813-1	65+ years	3 days	Developed an Acute nonoocclusive 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	JANSSEN	1125625-1	65+ years	4 days	3/11/21- pt was feeling fine. She stood up got dizzy and seamed 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 seamed 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	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 02 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 02 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	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	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	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. lt hemi clot found on ct angiogram & mri. 2nd mri found clot busted with residual. transfered to telemetry next nite. echo unconclusive. 02 sats low, venogram done 3days later show lt dvt, lung ct wnl. ld 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	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 Regul atory Authorities, Ethics Committees and Investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1078458-1	30-39 years	4 days	Blood clot in lung

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	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	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	1002441-1	65+ years	5 days	On morniing of 1/30/11 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	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 ex-ray. He saw a mass and told her to ho 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	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	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%. Transfered 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	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 lympocytic 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	JANSSEN	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	JANSSEN	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 sigmoid sinus with tentorial herniation. Patient developed brain herniation and brain death was pronounced on March 18th, 2021.
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	1026921-1	65+ years	6 days	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. 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
COVID19 VACCINE	MODERNA	1046684-1	40-49 years	6 days	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 >24hrs. DVT found on lower leg US 1/10/2021. Remain on DOAC for anticoagulation.
COVID19 VACCINE	MODERNA	1056972-1	65+ years	6 days	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.

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	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 popliteral/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	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	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 illiac, 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	1065976-1	65+ years	7 days	Pulmonary Embolus, hospitalized. Released by hospital 2 days after event. Blood Thinners and pain medication.
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 occuring after first COVID 19 vaccine dose. Was sent for duplex study which revealed acute deep vein thrombosis in right subclavian and axillary veins and superfficial 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	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	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, ckd, 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. Patent 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	1154151-1	65+ years	7 days	FALLS, CHEST PAIN, HEMORRAHAGIC 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	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	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	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	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	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	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	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 nonrebreather 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 symotoms.
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 sings 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	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	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	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	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	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	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 Eliqus and no intervention for removal of the thrombosis.
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	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	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 negatve 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	1077988-1	30-39 years	10-14 days	# AKI with non-nephrotic range proteinuia 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	1098756-1	65+ years	10-14 days	Patient has rt lower lobe Pulmonary emboli and rt popliteal dvt

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	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, colecalciferol (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 > 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: > 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.
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	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 clot 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	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	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	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,
COVID19 VACCINE	MODERNA	1041500-1	65+ years	15-30 days	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.
COVID19 VACCINE	MODERNA	1042458-1	65+ years	15-30 days	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.
COVID19 VACCINE	MODERNA	1052095-1	30-39 years	15-30 days	DVT left lower extremity

COVID19 VACCINE	MODERNA	1057548-1	50-59 years	15-30 days	bilateral pulmonary embolism; multiple areas of infarct; back pain; ateltheisis; 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, ateltheisis/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 20221, 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, ateltheisis/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	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	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 decrese since the 1/15 bloodwork Admitted for 3 nights on heparin dip. Discharge on home Lovenox injections for 30days.

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	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	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 innoculation.
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	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	1183418-1	65+ years	15-30 days	Vaccine breakthrough hospitalization - SOB with O2 sat 50% when EMS arrived. On non-rebreather satting 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, & tociluzumab. 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	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	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 thromboxis; 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	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.

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	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	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 runnying 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 aggreviated? 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	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	1146761-1	65+ years	15-30 days	"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""
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	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-Co-V-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	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	1109881-1	40-49 years	31-60 days	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.; 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	PFIZER\BIONTECH	1028567-1	40-49 years	31-60 days	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.
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	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	1065432-1	65+ years	61-120 days	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.

COVID19 VACCINE	NKNOWN MANUFACTUR	1167457-1	Unknown	61-120 days	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 anckle / foot was sore; pain in foot, calf and anckle / 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.

COVID19 VACCINE	JANSSEN	1157508-1	65+ years	Unknown	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).
COVID19 VACCINE	JANSSEN	1157533-1	Unknown	Unknown	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.

COVID19 VACCINE	JANSSEN	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	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 nonserious 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 Êpossibly 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 evens 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 embolis 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	PFIZER\BIONTECH	0912064-1	Unknown	Unknown	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.
COVID19 VACCINE	PFIZER\BIONTECH	0925634-1	Unknown	Unknown	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.""

COVID19 VACCINE	PFIZER\BIONTECH	1000489-1	Unknown	Unknown	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.
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 purply 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 purply 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 purply 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 clot on her left arm; on her left arm hurt real bad that's what the clot 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	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.

COVID19 VACCINE	PFIZER\BIONTECH	1048691-1	Unknown	Unknown	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.
COVID19 VACCINE	PFIZER\BIONTECH	1051004-1	50-59 years	Unknown	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.
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	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.""

COVID19 VACCINE	PFIZER\BIONTECH	1072538-1	65+ years	Unknown	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.
COVID19 VACCINE	PFIZER\BIONTECH	1076894-1	65+ years	Unknown	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.""

COVID19 VACCINE	PFIZER\BIONTECH	1090240-1	65+ years	Unknown	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 T0CL001021, 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
COVID19 VACCINE	NKNOWN MANUFACTUR	1012226-1	50-59 years	Unknown	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 & feet are swollen. Event Ongoing.

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Dataset: The Vaccine Adverse Event Reporting System (VAERS)
Query Parameters:
Date Report Received: Nov., 2020 to Apr., 2021
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: Apr 20, 2021 11:17:16 AM

Suggested Citation: Accessed at http://wonder.cdc.gov/vaers.html on Apr 20, 2021 11:17:16 AM

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 410 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).

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.

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 then 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 4/10/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. 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/