

VAERS Reports for COVID Vaccine Thrombosis / Blood Clots - March 26, 2021

Notes	Vaccine Manufacturer	Vaccine Type	Onset Interval	Adverse Event Description
	MODERNA	COVID19 VACCINE	0 days	Moderna COVID-19 Vaccine At 2 PM I went blind in my left eye. Went to emergency room at Hospital Was told I have Blood clot in my eye causing the blindness and Ophthalmologist says it will probably be permanent
	MODERNA	COVID19 VACCINE	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.
	MODERNA	COVID19 VACCINE	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.
	MODERNA	COVID19 VACCINE	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.
	MODERNA	COVID19 VACCINE	0 days	blood clot in left forearm; Sore arm; A spontaneous report was received from a consumer concerning a 78, year, old, female patient who developed a blood clot in the left forearm. The patient's medical history included hypertension, high cholesterol and hypothyroidism. On 19-JAN-2021 the patient had two stents placed in her heart. Products known to have been used by the patient, within two weeks prior to the event, included clopidogrel bisulfate (One 5 milligram AM and PM) and apixaban (One 5 milligram AM and PM) and Aspirin. On 10-FEB-2021, approximately six days prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number not provided) intramuscularly in the left arm for prophylaxis of COVID-19 infection. The patient had a sore arm for about a day after the vaccination. Six days later the left arm was red and swollen, inside forearm four inches down below the elbow it was stinging, slightly swollen, just to a soft touch she felt lumps of swelling. The patient went to the emergency room and had blood work and an ultrasound. The emergency room doctor told her that she had a blood clot in the left forearm four inches down below the elbow. The lab test done at the emergency were blood work and ultrasound. Treatment for the event included changing her current medication to one clopidogrel bisulfate 5 milligrams AM and PM and apixaban two tablets of 5 milligrams AM and PM and to discontinue the Aspirin for one week. There was no change planned to the dosing schedule of mRNA-1273 in response to the event(s) and is scheduled to get her second vaccination 10-MAR-2021. The outcome of the events were considered as unknown. Follow up: No follow up information received.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.

MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	0 days	Migraines have become more frequent and more intense to the point of were she could not function; Developed a welt at the injection site that she describes as COVID arm which was a 3-4inch raised circle underneath the injection site; Pain under lymph nodes; Developed thrombosis on her head, but it went away; A spontaneous report was received from a consumer on 04 Mar 2021 concerning a 45-years-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed thrombosis on her head, but it went away, migraines have become more frequent and more intense to the point of were she could not function, developed a welt at the injection site that she describes as COVID arm which was a 3-4inch raised circle underneath the injection site, lymph nodes pain, which she still has. The patient's medical history was not reported. Current conditions included migraine. The patient had allergy to latex and pineapple. No relevant concomitant medications were reported. On 14 Feb 2021, the patient received their first of two planned doses of mRNA-1273 (lot: not provided) intramuscularly in right arm for prophylaxis of COVID-19 infection. Since 14 Feb 2021, patient's migraines had become more frequent and more intense to the point of were she could not function. She also developed thrombosis on her head, but it went away. The patient also developed a welt at the injection site that she described as COVID arm which was a 3-4 inch raised circle underneath the injection site. She also developed pain under lymph nodes, which she still had. No treatment information was provided. Action taken with mRNA-1273 in response to the events was unknown. The event of migraines have become more frequent and more intense to the point of were she could not function and pain under lymph nodes which she still has were unresolved, the event of developed thrombosis on her head but it went away was resolved, while the outcome of the event of developed a welt at the injection site that she describes as COVID arm which was a 3-4inch raised circle underneath the injection site was unknown. The reporter did not provide an assessment for the events thrombosis on her head, but it went away, migraines have become more frequent and more intense to the point of were she could not function, developed a welt at the injection site that she describes as COVID arm which was a 3-4inch raised circle underneath the injection site, Pain under lymph nodes, which she still has.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.
MODERNA	COVID19 VACCINE	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
MODERNA	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	0 days	I had itching and redness and knots that formed in my left leg. The knots were at the site of a varicose vein. I sought tx at an ER on 12/26 to ensure it was not a blood clot. I followed up with my family dr on 1/4/2021 (When her office reopened) and was diagnosed with Superficial Thrombophlebitis. The knots remain in my leg. The redness has mostly gone away. My PCP felt as I recently had covid, the vaccine likely flared up the inflammation in my body and caused this condition.
PFIZER\BIONTECH	COVID19 VACCINE	0 days	Patient had fall x 2 with or without syncope (conflicting documentation) with humeral fracture after receiving the vaccine. Workup demonstrated PE and DVT (appears PE was not submassive/massive, unlikely it directly precipitated fall/ syncope)

PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	0 days	Patient reported as being altered, GCS 6 with noted aphasia around 1415.
PFIZER\BIONTECH	COVID19 VACCINE	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.""
PFIZER\BIONTECH	COVID19 VACCINE	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
PFIZER\BIONTECH	COVID19 VACCINE	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.

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

PFIZER\BIONTECH	COVID19 VACCINE	0 days	<p>right leg showed blood clot in lower back of leg from ankle to knee; right leg calf was red swollen and throbbled; Right leg ankle still hurt; flu symptoms appeared; Left arm, muscles, joints hurt; Left arm, muscles, joints hurt; Left arm, muscles, joints hurt; tired; chills; not feeling well; This is a spontaneous report from a contactable consumer (patient). A 70-year-old female non-pregnant patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EM9810), via an unspecified route of administration on 11Feb2021 10:00 at single dose in arm left for COVID-19 immunisation. There was no medical history and no known allergies. Concomitant medication included colecalciferol (D3) and multi vitamin. The patient did not have COVID prior vaccination. There was no other vaccine in four weeks. After about 4 hours after first Pfizer shot on a Thurs (11Feb2021), the patient experienced flu symptoms appeared, Left arm, muscles, joints hurt, chills, tired, not feeling well, on 11Feb2021 16:00. Right leg ankle still hurt after 24 hours Friday and Saturday by Sunday. Right leg calf was red swollen and throbbled on 14Feb2021 16:00. Monday (on 15Feb2021) the patient called physician and had sonogram on right leg which showed blood clot in lower back of leg from ankle to knee. Doctor put immediately on rivaroxaban (XARELTO) blood thinner for blood clot. Blood work has been done on 15Feb2021. The patient would follow up on 02Mar2021. She was concerned about taking second COVID vaccine dose on 04Mar2021. The adverse events resulted in Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. Covid was not tested post vaccination. The event outcome was unknown.</p>
PFIZER\BIONTECH	COVID19 VACCINE	0 days	<p>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.</p>

PFIZER\BIONTECH	COVID19 VACCINE	0 days	severe blockage in intestines, with gangrene, she is in bad shape, they contributed this to the clotting; Mesenteric artery thrombosis; severe tummy ache; she is losing weight; sore arm; body aches; This is a spontaneous report from a contactable consumer (patient's relative). A 77-years-old female patient received the second dose of BNT162B2 Pfizer-BioNTech COVID-19 mRNA Vaccine, via an unspecified route of administration in arm, on 09Feb2021, at 77 years of age, at single dose for COVID-19 immunization. Medical history included high blood pressure from an unknown date. Other than that, she was generally in good health, only on blood pressure medication and it was under control, no other issues. Historical vaccine included the first dose of BNT162B2 Pfizer-BioNTech COVID-19 mRNA Vaccine on 18Jan2021, at 76 years of age, after which she had regular sore arm and 24 hours body aches. The patient's concomitant medications included an unspecified blood pressure medication. On 09Feb2021 the patient experienced sore arm for 24 hours and little body aches; on 25Feb2021 she went out for coffee and cake, when she came back home, she had severe tummy ache after the meal, she rushed to the doctor and the doctor rushed her to the hospital on the same day. She was diagnosed with mesenteric artery thrombosis related to blood clot; she had severe blockage in intestines with gangrene (the intestines started dying), she was in bad shape and this contributed this to the clotting. The mesenteric artery thrombosis was assessed as life threatening and required patient's hospitalization on 25Feb2021. In response to the event the patient underwent an intestinal surgery: she was operated within an hour from her arrival to hospital as it was a life-threatening condition, they had to cut part of her intestines out because of gangrene. It was also reported that the patient was eating, but she was losing weight since an unknown date. The reporter didn't know the exact weight, but maybe it was 130 pounds. At the time of the report the event ""mesenteric artery thrombosis"" had not resolved yet and the patient was still hospitalized, the events ""sore arm"" and ""body aches"" resolved on 10Feb2021 and on an unknown date, respectively, whereas the outcome of all the other events was unknown. Information on the lot/batch number has been requested.""
PFIZER\BIONTECH	COVID19 VACCINE	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 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 received the vaccination and he was healthy, just old. I think that the shot killed him.
PFIZER\BIONTECH	COVID19 VACCINE	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 d-dimer which was elevated - and was admitted to the hospital for this since her vaccine - she has noticed increased chest tightness, SOB, hair loss, DVT/PE.""
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.

PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	0 days	chest pains; chest pains; blood clot; light headedness; low fever; blacked out for about 5 minutes; onset of major body ache and fatigue; onset of major body ache and fatigue; Body aches at injection site and into upper back; Body aches at injection site and into upper back; This is a spontaneous report from a contactable consumer (patient). A 67-year-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot Number: EN6200), via an unspecified route of administration, administered in left arm on 23Feb2021 10:30 AM (at age of 67 years old) as single dose for COVID-19 immunisation. Medical history included high cholesterol. Concomitant medications included atorvastatin; levobunolol (eye drops); latanoprost (LATANO). The patient previously received his first dose of BNT162B2 on 05Feb2021 for COVID-19 immunisation (brand=Pfizer; lot number: EL9269; administration time 03:30 PM; vaccine location=Left arm; dose number=1). 6 hours after injection on 23Feb2021, the patient experienced body aches at injection site and into upper back. After 24 hours after injection on 24Feb2021, started light headedness, low fever, blacked out for about 5 minutes, onset of major body ache and fatigue. Spent the next 36hrs in bed. 72hrs after injection recovered back to normal slowly. On 04Mar2021 at 8pm, started with chest pains called, admitted to Hospital with heart attack, immediately taken to Cardiac Cath Lab for coronary catheterization in both legs, to partial remove blood clot and insert continuous balloon pump, IV Heparin infusion Troponin 6542.3 ng/l (critical), NO previous health issues for blood clots. Discharged 07Mar2021, Apixiban 5mg twice a day, Clopidogrel 75 mg /day. AE resulted in: Emergency room/department or urgent care, Hospitalization, Prolongation of existing hospitalization (vaccine received during existing hospitalization), Life threatening illness (immediate risk of death from the event. Number days hospitalization: 3 days. The outcome of events was unknown.
PFIZER\BIONTECH	COVID19 VACCINE	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.
JANSSEN	COVID19 VACCINE	1 day	Heart was in A-fib, blood clot formed and had a Left Posterior Parietal Stroke
JANSSEN	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	1 day	Experienced shortness of breath upon minimal exertion 24 hours after having received the vaccine. Called MD 72 hours vaccine received - MD advised hospital ER. Admitted with pulmonary embolism and deep vein thrombosis. Remains short of breath and is on 4L of oxygen. Receiving anti-coagulants.

MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	1 day	Gross hematuria with clots. AKI with elevated creatinine to 2.18 (Baseline <1.0). UA with moderate blood, positive nitrite, moderate LE, >50 rbc's Urine 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.
MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	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.

MODERNA	COVID19 VACCINE	1 day	Saddle 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 'possibly related'
MODERNA	COVID19 VACCINE	1 day	DVT Right leg Femur
MODERNA	COVID19 VACCINE	1 day	Chief Complaint fever and chills, body aches x 3 days. also complains of intermittent chest pain since yesterday 02/20/21 10:28 History of Present Illness This is 31 year old male with no significant past medical history. Patient is health care provider and working in surgical center. Patient has COVID 19 second dose of vaccination on Wednesday and he was feeling sick after that including fever, chills and tiredness. He had chest pain started Thursday and which is in left side of the chest and mostly constant in nature and intensity was up and down and highest intensity was 7/10. No aggravating and relieving factor, denied any shortness of breath, leg swelling. He visited to urgent care and had 12 lead EKG and which showed ST changes in inferior lead and transfer to hospital ER. He is currently having pain about 1/10 intensity. He denied any nausea, vomiting, urinary and bowel symptoms. (sic) Assessment/Plan Chest pain with elevated troponin NSTEMI vs myocarditis post COVID 19 vaccination
MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	1 day	Four blood clots in left leg
MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	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
MODERNA	COVID19 VACCINE	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.

MODERNA	COVID19 VACCINE	1 day	Next day developed right leg pain. Following day diagnosed with a new deep venous thrombosis of the popliteal vein, right leg
MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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
PFIZER\BIONTECH	COVID19 VACCINE	1 day	Worsening arm pain after injection that eventually resulted in my being diagnosed with a blood clot in the arm that I received the injection on
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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 difficulty 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.
PFIZER\BIONTECH	COVID19 VACCINE	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 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."''''''
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.

PFIZER\BIONTECH	COVID19 VACCINE	1 day	Extensive left lower extremity/iliac DVT requiring surgical intervention. No history of thromboses. No family history of thromboses.
PFIZER\BIONTECH	COVID19 VACCINE	1 day	Diagnosed day after 2nd shot with ophthalmic artery thrombus causing vision loss/change in left eye. I did get shot series on 12/22/2020 #1 and 1/10/2021 and was diagnosed with Covid-19 on 12/13/2020. My internist MD did not feel the vaccine caused the thrombus /Stroke but I wanted to report it as it was associated with the vaccine administration (symptoms of vision loss within 24 hours of the vaccine #2 administration).
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.)
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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
PFIZER\BIONTECH	COVID19 VACCINE	1 day	Blood clot large in leg DVT and PE both lungs
PFIZER\BIONTECH	COVID19 VACCINE	1 day	After the second vaccine dose she reported not feeling well with unspecified symptoms for a few days. On February 18th, 2021 she visited her doctor with numbness in her hand. They thought it may be carpal tunnel and sent her home. The morning of March 18th, 2021 she had a severe stroke and was transferred to Hospital and then to other hospital. She was in the hospital until Tuesday March 23rd when she was transferred back to her home for hospice care. She died on March 26th, 2021.
PFIZER\BIONTECH	COVID19 VACCINE	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.

PFIZER\BIONTECH	COVID19 VACCINE	1 day	still have sore muscles in my shoulders; still feeling bad with all the above symptoms; 23Jan2021 went to get covid test but due to blood in my nose received antibody test which was neg; bad headache; winded; vomited; diaherria; coughing/cough; large clots gushed from my rt nostril went to er stopped bleeding after 2 hrs; large clots gushed from my rt nostril went to er stopped bleeding after 2 hrs; This is a spontaneous report from a contactable other hcp (patient). A 61-year-old female patient received their first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number: EL1283, expiry date not reported), via an unspecified route of administration on the left arm on 20Jan2021 18:45 at single dose for COVID-19 immunization. Medical history included diabetes mellitus and high BP from an unknown date and unknown if ongoing. Concomitant medications included levothyroxine, losartan potassium and sodium fluoride (CREST CAVITY PROTECTION). The patient previously took sepra and experienced allergies. The patient reported that on 21Jan2021, they woke up and brushed their teeth then at 6:40am blood with large clots gushed from their right (rt) nostril. The patient went to ER and stopped bleeding after 2 hrs. On 22Jan2021, the patient woke up with bad headache, winded, vomited, diaherria (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.
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	1 day	About 27-28 hours after injection felt strong pain in left lung area. Got progressively worse, especially at night when lying in horizontal position. The pain became extreme, could hardly breathe (inhalation causing extreme pain) and couldn't really walk on morning of March 6 (about 66 hours after vaccination. Called General Practitioner and he said to go to Emergency Rm. A catscan showed a small blood clot in each lung. Given blood thinner injection. Subsequent Ultrasound of legs showed no clots there. Released 48 hours later, put on Eliquis – 5mg – two each time, twice a day for 6 days, then one each time twice a day. for 3 months.
PFIZER\BIONTECH	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	10-14 days	ACUTE STEMI HEART ATTACK - VENTRICULAR FIBRILLATION - 99.9% BLOOD CLOT IN RIGHT CORONARY ARTERY

PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	10-14 days	1/4/21- Patient stated she had tenderness on the back of her left lower leg with redness then 1/8/21 started to have shortness of breath and made a doctor's appointment for 1/13/21. Seen by provider on 1/13/21 and was sent to ED and admitted to the hospital [ICU] with NSTEMI, acute deep, occlusive venous thrombosis left femoral vein and saddle embolus of pulmonary artery. Transferred to another acute care hospital for removal of thrombosis. Patient started on Eliquis and no intervention for removal of the thrombosis.
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	10-14 days	Sudden cardiac death. Autopsy report: right coronary artery thrombosis.
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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. Symptoms of embolism first appeared about 10 days following 2nd dose of Pfizer vaccine.
PFIZER\BIONTECH	COVID19 VACCINE	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
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	10-14 days	Stroke on January 20th, 2021. Unknown cause for blood clot.
PFIZER\BIONTECH	COVID19 VACCINE	10-14 days	# AKI with non-nephrotic range proteinuria and microscopic hematuria # Neutrophilia # Fevers # Normocytic anemia # Thrombocytosis # Coagulopathy # RUE Superficial venous thrombosis # Subconjunctival hemorrhage # Flame hemorrhage R fundus # Mild iridocyclitis # CRP elevation # Procalcitonin elevation # D Dimer elevation # Anasarca # Elevated BNP # Hypoalbuminemia # Small pericardial effusion # Elevated alk phos, bilirubin (direct predominant), and AST # Elevated lipase # Hypocomplementemia with low CH50 # Elevated IL2 Receptor (8540) # Aseptic meningitis w CSF with lymphohistiocytic predominant pleocytosis (25 nuc cells with 49% lymphs, 35% histiocytes, 16% pmn, glucose 41, protein 155 with neg meningoencephalitis panel)
PFIZER\BIONTECH	COVID19 VACCINE	10-14 days	Patient has rt lower lobe Pulmonary emboli and rt popliteal dvt

PFIZER\BIONTECH	COVID19 VACCINE	10-14 days	<p>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.</p>
PFIZER\BIONTECH	COVID19 VACCINE	10-14 days	<p>severe thrombocytopenia; Bleeding at Impella insertion site; peripheral swelling in hands/feet; cardiogenic shock; myocarditis; hypoxic respiratory failure; mural thrombus; hypotensive despite pressors; fever; cough; myalgias; This is a spontaneous report from a contactable physician. A 46-year-old non-pregnant female patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Lot number and Expiration date was not provided), intramuscularly on 05Feb2021 as a single dose for COVID-19 immunisation. The patient's medical history included hyperlipidemia and COVID-19 pneumonia from an unspecified date in Jan2021 to an unspecified date in Jan2021 (the patient was diagnosed with COVID-19 pneumonia prior to the vaccination. Recovered. Returned to work on 25Jan2021). Concomitant medications included atorvastatin orally at 10 mg, once a day, acetylsalicylic acid (ASPIRIN) orally at 81 mg, once a day, 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.</p>
MODERNA	COVID19 VACCINE	15-30 days	<p>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).</p>

MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	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. They 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 severe 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 severe muscle pains persisted and I was basically incapacitated during my entire stay at Hospital. Hospital had several specialists see me from Internal Medicine, Infectious Disease, Neurology to Rheumatoidologist and none of them found anything wrong with me other than my COVID anti-bodies were enormously high with no signs of slowing down. The conclusion by each of the specialist is that my symptoms all point to an Adverse Level 3 Inflammatory Reaction to the first COVID Vaccine shot. The Infectious Disease specialists emphasized that I DO NOT get the second vaccine shot since it would like have killed me. (We had cancelled my 2nd shot, scheduled for February 3, 2021 via Cancer Center the week of January 30, 2021.) Hospital concluded that they could not do anything further for me since all their extensive testing all came up negative other than the COVID antibody levels and started me on the same steroid via IV on February 10, 2021 and on February 11, 2021 I was released from Hospital with a 28-day gradual reduction of the steroid over that timeframe to see if the COVID antibody production would simply stop. They had no other recourse or follow up with for any of the specialists. I'm on my own at this point and scared. To help with the inflammation the only thing my wife and I saw we could do is see a health and well Doctor to try and purge myself of the inflammation and assist my bowel and liver health with trying to rid me of the vaccine and hopefully the antibody production. I'm on a strict diet and taking supplements to assist in the reduction of inflammation and cleaning my system out. Starting today, February 18, 2021 I start stepping back on the steroids prescribed by Hospital and praying that the symptoms and pain simply go away but I'm still having night sweats, weak and shaky.
MODERNA	COVID19 VACCINE	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.

MODERNA	COVID19 VACCINE	15-30 days	DVT left lower extremity
MODERNA	COVID19 VACCINE	15-30 days	<p>bilateral pulmonary embolism; multiple areas of infarct; back pain; atelthesis; 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, atelthesis/atelectasis, left leg pain, and deep vein thrombosis. The patient's medical history included daily exercise and no personal or family history of clotting issues and no trauma. Products known to have been used by the patient were not provided. On 02 Jan 2021, prior to the onset of the events, the patient received the first of two planned doses of mRNA-1273 (Lot number: 039k20-2a) intramuscularly for prophylaxis of COVID-19 infection. On 30 Jan 2021, approximately 28 days after the first dose, and prior to the onset of symptoms, the patient received the second of two planned doses of mRNA-1273 (Lot number: 012m20a) intramuscularly for the prophylaxis of COVID-19 infection. On 30 Jan 2021, the patient reports that for the first 18 hours, he experienced fever, chills and myalgia. On 01 Feb 2021, the patient reports that he thought the myalgia was continuing, as he had pain in his chest and back. The chest pains gradually worsened. On 05 Feb 2021, the patient went to the emergency room and was admitted. He was diagnosed with a pulmonary embolism. He was started on enoxaparin sodium but switched to apixaban. A computerized tomography study of the lungs showed that he had bilateral pulmonary embolism, multiple areas of infarct and atelectasis. His dimer was 4800. COVID-19 test was negative. An echocardiograph was performed, no results were reported. An ultrasound of the legs was performed and ruled out deep vein thrombosis. Date of discharge was not specified. On an unknown date two days after discharge, the patient experienced left leg pain and returned to the emergency department. Patient was diagnosed with deep vein thrombosis that ran the entire length of the femoral artery. Patient was switched back to enoxaparin sodium and taken off the apixaban. A repeat computerized tomography study was done to see if the pulmonary embolism was progressing and it was not, however, it showed pulmonary effusions. All current lab work was reported as normal, except for an increased prothrombin time. COVID-19 test was negative. Patient continues to be followed by a pulmonologist and hematologist. Consent to contact patient, pulmonologist and hematologist was obtained. Action taken with mRNA-1273 was not applicable. The outcome of the events, fever/pyrexia, chills, myalgia, chest and back pains, bilateral pulmonary embolism/pulmonary embolism, multiple areas of infarct/pulmonary infarct, atelthesis/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.</p>
MODERNA	COVID19 VACCINE	15-30 days	<p>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.</p>
MODERNA	COVID19 VACCINE	15-30 days	<p>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.</p>
MODERNA	COVID19 VACCINE	15-30 days	<p>After 1st injection (1/11/21) experienced severe shortness of breath with minimal activity with accelerated heart rate and drop in O2 stat. within 2 days of injection then developed wheezing cough. Primary MD prescribed Augmentin nd prednisone with eventual success. With normal blood work, chest x-ray and negative Covid test all done by 1/15. On 3/9/21 (28) days after second dose (2/11/21) experienced burning and swelling on right leg. Went to Hospital, ER and found extensive blood clots in right leg and saddle pulmonary embolism. Also had 50% Platelet blood count decrease since the 1/15 bloodwork Admitted for 3 nights on heparin dip. Discharge on home Lovenox injections for 30days.</p>

MODERNA	COVID19 VACCINE	15-30 days	Death on March 8 due to a large blood clot at the base of his brain. This was 16 days after inoculation.
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	15-30 days	Heavy period with more bleeding. And cramping and multiple clots
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	15-30 days	DVT and probable pulmonary embolus based on hypoxia Patient is physician who cares for patients in NH and ALF where there is documented COVID First dose COVID vaccine 12/20/20, second dose 1/10/20 Some shortness of breath developed about 1/10, not severe 1/30 Leg pain, fever to 101.6 abrupt onset extreme fatigue, ER eval 1.31 negative eval including neg rapid and PCR COVID tests Persistent sx led to repeat ER eval including LE dopper confirming occlusive femoral vein thrombosis; no hypoxia at rest but desat to 85% on exertion (climbing one flight of steps) Started anticoagulants 2/4/21 on home treatment; not working since 1/30/21
PFIZER\BIONTECH	COVID19 VACCINE	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
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	15-30 days	Left upper extremity DVT and pulmonary embolism diagnosed 2/24/2021. Arm swelling started 02/23/2021.

PFIZER\BIONTECH	COVID19 VACCINE	15-30 days	<p>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# EJI283), 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.</p>
PFIZER\BIONTECH	COVID19 VACCINE	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
PFIZER\BIONTECH	COVID19 VACCINE	15-30 days	DVT blood clot in the right foot, then spread to lower leg and knee and thigh, groin
PFIZER\BIONTECH	COVID19 VACCINE	15-30 days	Pericardial effusion; multiple blood clots in portal vein.
PFIZER\BIONTECH	COVID19 VACCINE	15-30 days	2/27/21 Sudden cardiac arrest due to thrombosis in the LAD
PFIZER\BIONTECH	COVID19 VACCINE	15-30 days	Left femoral DVT
PFIZER\BIONTECH	COVID19 VACCINE	15-30 days	Starting on February 24, 2021, I started to have shortness of breath. This slowly got worse until on March 2, 2021 I was unable to breathe in all the way and was getting a sharp pain in my side/back when I tried to breathe in more than half way. I then went to the emergency room recognizing the symptom as likely being a pulmonary embolism, as I had experienced one four years earlier. It was, in fact, a PE. I was in the hospital for five days as they treated the clots with blood thinners. I slowly got my breathing more back to normal and was discharged. They are still running myriad tests to try to determine the cause or causes, but I thought it wise to report here in case the vaccine is a factor. I received my second dose on 2/26/21, a few days before I went to the hospital but my symptoms started a few days before that.
PFIZER\BIONTECH	COVID19 VACCINE	15-30 days	<p>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, severe 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/flu/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 steroid IV. Within first 36 hours the extreme lung pain disappeared and I got better. I do have cats scan, mri, X-rays from stay. Cat scan clear, X-ray, normal, mri-classic ms history. Was this Ms event? I'm not sold as I didn't have other normal MS flare symptoms. Was this injection aggravated? Perhaps... I'm sharing this because I think tracking autoimmune disease people is important data gathering. Feel free to call if more dialogue is necessary</p>

PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	2 days	Vaccine admin Wed 3 pm. Thurs no problem. Friday am, patient woke up almost fully blind right eye.
MODERNA	COVID19 VACCINE	2 days	Thrombosis, right hepatic vein, Hepatic Abscess (10 cm)
MODERNA	COVID19 VACCINE	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
MODERNA	COVID19 VACCINE	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)
MODERNA	COVID19 VACCINE	2 days	Central venous sinus thrombosis
MODERNA	COVID19 VACCINE	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.

MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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 Xarelto. Not sure if it was related but I have had no history of blood clots. 2 years previously broke my right patella and was with brace and no weight bearing for about 8 weeks and brace for 12 weeks without clot issues. Traveled by car a couple thousand miles last year and no issues.
MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	3 days	Pt received vaccine and within 72 hrs developed a stroke. Low platelet count. Endocarditis. Emboli to liver, spleen, kidney.
MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	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.""

PFIZER\BIONTECH	COVID19 VACCINE	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.""
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	3 days	Back pain, bilateral PE and DVT
PFIZER\BIONTECH	COVID19 VACCINE	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.

PFIZER\BIONTECH	COVID19 VACCINE	3 days	<p>On day 04 After receiving the 2nd Covid 19 Pfizer vaccine, I experienced a deep pain in my upper inner right thigh around 0600 am of the 16th of January. At the same time my calf muscle of that same right leg was in pain. I thought it to be muscular pain as I was told by the reading material regarding symptoms of the covid 19 vaccine there could be aches and 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 occurred 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. 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 and 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 occurred 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 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 didn't appear to be interested in further diagnosis and made sure I had the paperwork to track the results of my Covid swab sent to the lab. The visit was completed and I was released to go back to work/home. I carried on the symptoms of the shortness of breath from the 19th of January to the 22nd of January monitoring my O2 (oxygen levels) with a pulse oximeter. They ranged from 90-93. On the evening of the 22nd of January I was becoming very uncomfortable with my breathing climbing the stairs in my home and monitored my O2 readings with the oximeter on my finger when walking upstairs and they dropped down to 60-65. My wife drove me to the emergency room at Hospital. I walked into the ER and checked myself in for shortness of breath and leg pain in my right leg. I was admitted into the emergency room and put on 15 litres of oxygen. The emergency room Dr ordered a chest Xray, Cat Scan of my chest and heart and a sonogram of my right leg. The testing results came back with a noted large pulmonary emboli on my lungs/heart area and blood clots throughout my right leg (right lower extremity DVT). Surgery was performed to remove the pulmonary emboli and I was put on a Heparin Drip to thin out my blood for the remaining clots in my chest and my right leg. The attending physician ordered a T.E.E. (transesophageal Echocardiogram) to observe my heart functions. I was told the TEE did not demonstrate any further recommend surgeries. I was administered a test for my cardio and heart functions prior to my discharge on 27 January 2021. I was prescribed Eloquis for maintenance medication to be monitored by followup visits to my cardiologist and Hematologist within the next few weeks. I have no family or personal history of Blood Clots. I do perform administrative duties as part of my job, which requires sitting and working on a computer. Note however I move around very often during a work day and operate a farm tractor and have an active life style. I have not recently had any extended trips more than 2 hours nor have I flown within the past year or so.</p>
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	3 days	Deep Venous Thrombosis of Right Axillary and Subclavian vein. Treated with IV Heparin Drip.
PFIZER\BIONTECH	COVID19 VACCINE	3 days	THROMBOTIC STROKE IN THE DISTRIBUTION OF THE LEFT MCA DISTRIBUTION
PFIZER\BIONTECH	COVID19 VACCINE	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
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	3 days	Developed an Acute nonocclusive DVT in left leg 10 days after my first vaccine. Decided to decline my second vaccine. I do have a history of having blood clots, but last one was 32 years ago.
PFIZER\BIONTECH	COVID19 VACCINE	3 days	Stroke on 2/11/2021 caused by a blood clot

MODERNA	COVID19 VACCINE	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
MODERNA	COVID19 VACCINE	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: Doppler on Right leg and CT with contrast of chest 2/24: admitted to hospital for bilateral PE and DVT in RLE
MODERNA	COVID19 VACCINE	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
PFIZER\BIONTECH	COVID19 VACCINE	31-60 days	CVA/thrombotic event. R sided weakness and sensory deficit. No preexisting risk factors. Hypercoagulable work up negative. Managed conservatively. Improvement without resolution of symptoms to date.
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	31-60 days	DEATH Narrative: patient's wife reported he had gone in an outside hospital, had held his briliata as advised anticipating shoulder surgery ""and he threw a big clot and died."""
JANSSEN	COVID19 VACCINE	4 days	3/11/21- pt was feeling fine. She stood up got dizzy and seemed to have a seizure. when she came to she did not know that it had happened. about 5 hours later she stood up again got dizzy and seemed to have had another seizure. her husband called 911. EMTs took her vitals but did not detect anything to be wrong at the time and was advised to see PCP. Next day 3/12/21 she went to her PCP. She had blood work which showed high enzymes for heart failure so was sent to hospital to be admitted. Pt had blood work, chest xray which showed blood clots in both lungs. She was administered blood thinner. MRI of head was clear. Echocardiogram was clear. Pt stayed about 4 days. Enzymes for heart failure was clearing up. Pt was released and had a FU appt w/ PCP on 3/22/21. Pt found out that she also had bilateral deep vein thrombosis in both legs while she was in the hospital. Pt is improving and is almost back to normal.
JANSSEN	COVID19 VACCINE	4 days	Within a week of getting the vaccine I developed a blood clot in the lining of my stomach
MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	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
MODERNA	COVID19 VACCINE	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 area 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.
MODERNA	COVID19 VACCINE	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 breathe, oxygen saturation 83%, could not walk across the room without gasping for air, which lasted for about 2 days. Could not reach her PCP due to holidays, was convinced she had COVID. Went to drive-thru facility and got the COVID test on 12/28/20, negative on 12/29/20. Then made another APT, went back on 12/30/20 had negative test again. On 12/30/20 started feeling better, was not great but her O2 SAT's were about 90. Stayed that way until 1/8/21, had FU from lumpectomy with surgeon, when she got up her left ankle/foot were very swollen and red looking. Saw that Dr., and discussed the postop business and showed her the foot/leg told her to have it looked at. Her PCP was closed, she went to radiology Dept in Hospital and found DVT in her left leg. She was then told to go to the ER and ordered a CT scan, which showed pulmonary emboli in both lungs. Put on heparin IV right away, later transferred to another hospital where CV surgeon on staff. By that evening they decided that she was walking, talking and checking blood levels, kept her overnight and sent her home the next day. Needed to be on blood thinners, and saw pulmonologist. Has APT with hematologist this week. Pulm told her to call and report adverse reaction. Today, 1/26/21 her O2 SAT's are in the 99%, leg is still swollen, and is able to breathe 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.

MODERNA	COVID19 VACCINE	4 days	blood clot in lungs, PE,
MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	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
PFIZER\BIONTECH	COVID19 VACCINE	4 days	5:30 am I found husband by bed, babbling, Called 911, Had Lt Hemi Stroke. Aphasic, Rt side limp, given TPA. Sent to ICU. Recovered within 2hrs, speech, movement of extremities. It hemi clot found on ct angiogram & mri. 2nd mri found clot busted with residual. transfered to telemetry next nite. echo unconvulsive. 02 sats low, venogram done 3days later show lt dvt, lung ct wnl. Id asa & b/p meds were given. blood work to be drawn for baseline prior to anticoagulant therapy. possible d/c 9/30.
PFIZER\BIONTECH	COVID19 VACCINE	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).
PFIZER\BIONTECH	COVID19 VACCINE	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 (ischemic stroke) on 26Jan2021 05:30 with outcome of unknown, right paralysis on an unspecified date with outcome of unknown. The patient was hospitalized for DVT (deep vein thrombosis) and stroke from 26Jan2021 to 30Jan2021. The patient underwent lab tests and procedures including blood pressure diastolic: 84 mmhg on 30Jan2021, blood pressure systolic: 141 mmhg on 30Jan2021, body mass index: 26.4684 kg/m2 on 26Jan2021, body temperature: 98.2 °F on 30Jan2021, heart rate: 55 bpm on 30Jan2021, magnetic resonance imaging: acute left parietal lacunar infarct, Lower extremity ultrasound: left popliteal vein DVT, oxygen saturation: 95 % on 30Jan2021, respiratory rate: 18 br/min on 30Jan2021. The reporter considered the reported events to be possibly related to BNT162B2 vaccine. Follow up information has been requested.; Sender's Comments: Based on the limited information currently available, a possible contributory role of the suspect drug in the reported events cannot be completely excluded given the known suspect drug profile and/or implied temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.
PFIZER\BIONTECH	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	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).
MODERNA	COVID19 VACCINE	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

MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	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).
MODERNA	COVID19 VACCINE	5 days	Trouble breathing, severe fatigue, blood clots in lung and leg.
MODERNA	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	5 days	Visited Provider appx 500 pm 1.14.2021 DVT - left calf - 2 clots via ultrasound on Eliquis now
PFIZER\BIONTECH	COVID19 VACCINE	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 donazepam. 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.
PFIZER\BIONTECH	COVID19 VACCINE	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.
JANSSEN	COVID19 VACCINE	6 days	Diagnosis: Cortical vein thrombosis, massive intracerebral hemorrhage with tentorial herniation, thrombocytopenia. Clinical Presentation and Course: 1 week after receiving Janssen COVID19 vaccination, patient developed gradually worsening headache. On March 17th, patient presented to Hospital with dry heaving, sudden worsening of headache and L sided weakness. Evaluation with head CT revealed a large R temporoparietal intraparenchymal hemorrhage with 1.3cm midline shift. She ended up getting intubated for worsening mental status. On evaluation at arrival in Medical Center, she was noted to have extensor posturing. Repeat imaging revealed worsening midline shift to 1.6cm. CTA showed cortical vein thrombosis involving the right transverse and sigmoid sinus with tentorial herniation. Patient developed brain herniation and brain death was pronounced on March 18th, 2021.
MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	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.

MODERNA	COVID19 VACCINE	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
PFIZER\BIONTECH	COVID19 VACCINE	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
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	7 days	One week after the shot (1-14-2021) Patient (19 y.o.)reported side pain and appeared constipated, Laxatives given along with Tylenol, on further assessment Patient was noted to have left leg redness and abdominal fullness. Dr. was updated and we had orders for close monitoring, the next day when she got up, her leg appeared better, and she had passed a small BM, but by lunch she had developed significant pain and edema in her left leg, and the color of her leg was reddened again. She was sent to the emergency room with her symptoms. She was admitted back to our facility yesterday, her diagnoses included Acute provoked left external iliac, femoral, popliteal, and peroneal DVT. Elevated Factor II levels, Elevated APC resistant, May-Thurner Syndrome, history of developmental disabilities, fecal impaction and urinary retention - suspected related to her fecal impaction. Vascular surgery was consulted, and pt. was started on a heparin drip, and mechanical thrombectomy was needed for both legs due to multiple clots. She was started on Eliquis and Plavix, and thigh high compression stockings were ordered, ace wraps being used until these are supplied. Her Fecal impaction was addressed also and the urinary retention resolved.
MODERNA	COVID19 VACCINE	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
MODERNA	COVID19 VACCINE	7 days	Site: Swelling at Injection Site-Severe, Systemic: DVT-Severe, Additional Details: Patient presented to office with swelling of right upper extremity occurring after first COVID 19 vaccine dose. Was sent for duplex study which revealed acute deep vein thrombosis in right subclavian and axillary veins and superficial thrombophlebitis of basilic vein in right arm. Pharmacy was contacted 3/10/2021 by MD at hospital to report vaccine adverse event

MODERNA	COVID19 VACCINE	7 days	<p>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.</p>
PFIZER\BIONTECH	COVID19 VACCINE	7 days	<p>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.</p>
PFIZER\BIONTECH	COVID19 VACCINE	7 days	<p>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. Patient thus far has tested negative. Doppler lower extremity revealed Acute occlusive vein thrombosis of the entire course of the gastrocnemius vein and soleal vein. Patient received covid vaccine on 1/4/21. Patient has several risk factors for clot - age, previous CVA, hx of prostate cancer. Also had positive covid exposure though tested negative""</p>
PFIZER\BIONTECH	COVID19 VACCINE	7 days	<p>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)</p>
PFIZER\BIONTECH	COVID19 VACCINE	7 days	<p>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.</p>
PFIZER\BIONTECH	COVID19 VACCINE	7 days	<p>patient developed blood clot in her left groin one week after getting first COVID19 vaccine.</p>
PFIZER\BIONTECH	COVID19 VACCINE	7 days	<p>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.</p>
PFIZER\BIONTECH	COVID19 VACCINE	7 days	<p>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.</p>

PFIZER\BIONTECH	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	8 days	ER admission on February 27th, discharged with a diagnosis of Bilateral Pulmonary Embolism and DVT of lower limb
MODERNA	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.

PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.
JANSSEN	COVID19 VACCINE	9 days	Patient developed an extensive acute, occlusive thrombus in the external iliac, common femoral, popliteal, and gastrocnemius veins
JANSSEN	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	9 days	Patient (myself) developed DVT/PE diagnosed on 1/4/2021
MODERNA	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.

PFIZER\BIONTECH	COVID19 VACCINE	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.
MODERNA	COVID19 VACCINE	Unknown	PE; DVT; A spontaneous report was received from a pharmacist concerning patient (age and gender unknown) who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced a pulmonary embolism (PE) and deep vein thrombosis (DVT). The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On an unknown date, the patient received the first of two planned doses of mRNA-1273 (Batch number not provided) intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, the patient experienced a PE and DVT. Treatment information was not provided. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the events, PE and DVT, were not reported.; Reporter's Comments: Very limited information regarding the reported events have been provided at this time. No additional information is expected as consent to follow up was denied.
MODERNA	COVID19 VACCINE	Unknown	Pulmonary Embolism Narrative: Patient was hospitalized with acute pulmonary embolism on 2/12/2021. Was started on Eloquis and discharged on 2/15/2021, with primary diagnosis of acute PE and BLE DVT. Secondary diagnosis of acute systolic heart failure with bilateral pleural effusions. On 2/17 we got notification that patient was placed on hospital.
PFIZER\BIONTECH	COVID19 VACCINE	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.""
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	Unknown	confirmed about a blood clot/check me for a blood clot, I didn't have one but it was kind of like a thrombosis kind of thing; Both of my legs, lower part of my legs were swollen that night when I went to bed and they got really red, almost purple red; Both of my legs, lower part of my legs were swollen that night when I went to bed and they got really red, almost purple red; This is a spontaneous report from a contactable consumer (patient). A patient of unspecified age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number and expiry date: not known), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The consumer stated that after the first vaccine and it might be coincidental, the patient was not sure because the patient didn't know what to expect. Both of the patient's legs, lower part of the patient's legs was swollen that night (unspecified date) when the patient went to bed and they got really red, almost purple red and the patient stayed that way for a couple of days. The patient went to see the doctor two days later and doctor confirmed about a blood clot, so they did check the patient for a blood clot; the patient didn't have one, but it was kind of like a thrombosis kind of thing. So, the doctor put the patient on antibiotics for that. The patient asked if it is related to the shot, the patient didn't know it happened the same day the patient got the shot; so, the patient didn't know about that. The outcome of the events was unknown. Information on the Lot/Batch number has been requested.

PFIZER\BIONTECH	COVID19 VACCINE	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
PFIZER\BIONTECH	COVID19 VACCINE	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:
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.

PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.
PFIZER\BIONTECH	COVID19 VACCINE	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.

PFIZER\BIONTECH	COVID19 VACCINE	Unknown	<p>bilateral blood clots in legs that then went to lungs then went into BLAST crisis; bilateral blood clots in legs that then went to lungs then went into BLAST crisis; Patient with myeloid leukaemia (CML) and WBCs abnormal received BNT162B2; Patient with myeloid leukaemia (CML) and WBCs abnormal received BNT162B2; This is a spontaneous report from a contactable consumer (patient). An 82-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Solution for injection (lot number and expiration date unknown) via an unspecified route of administration in the left arm on 02Feb2021, 13:00PM (at 82 years old) at a single dose for COVID-19 immunization. The patient was vaccinated in the Nursing Home/Senior Living Facility. The patient's medical history included myeloid leukaemia (CML) diagnosed a few months earlier, WBCs abnormal, blood pressure, and heart surgery valve repair. The patient has no known allergies. Concomitant medications included atorvastatin, carvedilol, vitamin d nos, dasatinib monohydrate (SPRYCEL) from an unknown date to help get WBCs back in normal range; cyanocobalamin (VITAMIN B12), and cetirizine hydrochloride (ZYRTEC), all were received within 2 weeks of vaccination. At 82 years old, the patient received the first dose of BNT162B2 (lot number and expiration date unknown) via an unspecified route of administration in the left arm on 12Jan2021 at a single dose for COVID-19 immunization. The patient was not diagnosed with COVID prior to vaccination and did not receive any other vaccines within 4 weeks prior to BNT162B2. It was unknown if patient was tested for COVID post vaccination. On Friday (unknown date in Feb2021), patient's WBC was 150,000 and on Saturday (unknown date in Feb2021), patient had bilateral blood clots in legs that then went to lungs then went into BLAST crisis. The adverse events resulted in emergency room/department or urgent care as well as hospitalization due to life threatening illness (immediate risk of death from the events). The patient was hospitalized for 12 days. Therapeutic measures which include steroids, blood thinners, and lots of other meds were administered. Outcome of the events ""patient's WBC was 150,000"" and ""bilateral blood clots in legs that then went to lungs then went into BLAST crisis"" was recovering. Information on the lot/ batch number has been requested.""</p>
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PFIZER\BIONTECH	COVID19 VACCINE	Unknown	<p>Cardiac arrest; Pulmonary embolus; Renal failure; Fever; Dehydration; Not eating or drinking; COVID-19 confirmed by positive COVID-19 test / COVID pneumonia; blood clot; blood pressure was low; Respiratory arrest; Respiratory failure; Hypoxemia; ventricular tachycardia; This is a spontaneous report from a contactable nurse reporting on behalf of the husband. A 71-year-old male patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EL9264) on 10Feb2021 at about 19:00 (at the age of 71 years), in left deltoid, for COVID-19 immunisation. No other vaccines were given on the same day or within 4 weeks. The patient declined flu vaccine and pneumococcal vaccine (PNEUMOVAX), he had never had another vaccine except maybe his childhood vaccines. Medical history included rotator cuff surgery and cataract removed in 2020. The patient exercised regularly, he was healthy, he walked for miles and didn't eat any non-sense, he did not eat out, he did not smoke. The patient's mother was 100 years old and fully competent. The patient had two sisters older than him, the oldest one had hypertension the second sister did not have anything that they were aware of. The patient's father lived until he was 98 years old. The patient concomitant medications were none. The patient was told to take vitamin D 50,000 units but didn't even take them (he still had 9 of them in the bottle and they gave him 13). The patient experienced fever on 11Feb2021, renal failure on 14Feb2021, pulmonary embolus on 28Feb2021, cardiac arrest on 04Mar2021, dehydration and not eating or drinking on an unspecified date in Feb2021. These events required ER visit and were reported as serious as involved hospitalization from 14Feb2021 to 04Mar2021 and as fatal events. The patient died on 04Mar2021. Clinical course of the events included the following information. The patient received the first vaccine on 10Feb2021, the next day he developed a fever. The reporter spoke with the patient's doctor who told to give the patient paracetamol (TYLENOL) thinking the fever was from the vaccine. On 12Feb2021 and 13Feb2021, the patient's temperature was 102. Then the doctor advised to take the patient to the hospital. The patient's temperature was still 102, he was in renal failure, and they had to dialyze him. The patient was otherwise healthy, the patient's last physical was in Dec2020 and the only thing it showed was that his A1C was 5.7. The patient had no cholesterol or hypertension. The doctor advised the patient to decrease sugar and carbs because the holidays were coming up. The patient's follow up was scheduled on Mar2021. The reporter felt that the vaccine has something to do with the patient renal failure. The reporter spoke with the doctors at the hospital who didn't want to commit to anything. The reporter believed this was an adverse event. The caller mentioned that she had her vaccine before and she was fine. The patient was admitted on 14Feb2021 and by Wednesday he was not eating or drinking, he was dehydrated. The patient's admitting diagnoses was elevated temperature and ruling out COVID. The patient tested positive for Covid on 14Feb2021 (COVID-19 PCR test). The patient's temperature was 99.8 and then kept creeping up, on Saturday it was 102. The caller gave the patient Tylenol cold and flu (lot TOCL001021, expiry date Oct2021) took the edge off but in three hours the temperature was back up again. The patient never complained of pain and didn't want to take Tylenol. On 15Feb2021 the patient's numbers were getting better after the fluid challenge and then his numbers kept creeping up after that. The patient had the fever a week until they had it under control. The fever went away, it was gone for like 5 days, then it spiked again. The patient was started on piperacillin/tazobactam (ZOSYN) for like 3 or 5 days and the fever went away but then it kept getting worse. On 28Feb2021, the medical personnel thought the patient had a pulmonary emboli but because of the renal failure, they couldn't do a computerized tomography on the patient. The doctors mentioned that the patient was in renal failure and they thought they heparinized the patient and he had a blood clot who led to pulmonary embolus, cardiac arrest, and death. The patient was diagnosed with a pulmonary emboli on 28Feb2021. The patient started de-saturating and the doctors intubated and sedated him that whole time until this. Dialysis was started on 01Mar2021 and the patient received it every day except 04Mar2021. The patient's blood pressure was normal, it hardly ever went above 120. The patient was on the medical floor from 22Feb2021 to 04Mar2021. When the patient was on the medical surgical floor, he was on high flow 5 liters. After the patient started desaturating, he went to the intensive care unit and was put on a non-rebreather on 45%. The patient's highest heart rate was after intubation was 135, but the patient's blood pressure was low so they started him on some vasopressors. They did the</p>
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Dataset: The Vaccine Adverse Event Reporting System (VAERS)

Query Parameters:

State / Territory: The United States/Territories/Unknown

Symptoms: AORTIC THROMBOSIS; ARTERIAL THROMBOSIS; ARTERIAL THROMBOSIS LIMB; ATRIAL THROMBOSIS; AXILLARY VEIN THROMBOSIS; BASILAR ARTERY THROMBOSIS; BRACHIOCEPHALIC VEIN THROMBOSIS; CAROTID ARTERY THROMBOSIS; CAVERNOUS SINUS THROMBOSIS; CEREBRAL ARTERY THROMBOSIS; CEREBRAL THROMBOSIS; CEREBRAL VENOUS SINUS THROMBOSIS; CEREBRAL VENOUS THROMBOSIS; CORONARY ARTERY THROMBOSIS; DEEP VEIN THROMBOSIS; EMBOLISM; HAEMORRHAGE URINARY TRACT; HEPATIC VEIN THROMBOSIS; ILIAC ARTERY THROMBOSIS; INJECTION SITE THROMBOSIS; INTRACARDIAC THROMBUS; INTRACRANIAL VENOUS SINUS THROMBOSIS; JUGULAR VEIN THROMBOSIS; MESENTERIC ARTERY THROMBOSIS; MESENTERIC VEIN THROMBOSIS; OPHTHALMIC ARTERY THROMBOSIS; OPHTHALMIC VEIN THROMBOSIS; PELVIC VENOUS THROMBOSIS; PERIPHERAL ARTERY THROMBOSIS; PORTAL VEIN THROMBOSIS; PULMONARY ARTERY THROMBOSIS; PULMONARY THROMBOSIS; 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 THROMBOSIS; VENOUS THROMBOSIS; VENOUS THROMBOSIS LIMB

Vaccine Products: COVID19 VACCINE (COVID19)

VAERS ID: All

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

Show Totals: False

Show Zero Values: Disabled

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

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Query Date: Apr 2, 2021 3:06:51 PM

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Suggested Citation: Accessed at <http://wonder.cdc.gov/vaers.html> on Apr 2, 2021 3:06:51 PM

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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 229 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.

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Footnotes:

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

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Caveats:

1. <p> 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. </p> <p> 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. </p> <p> 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. </p>

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3. Some items may have more than 1 occurrence in any single event report, such as Symptoms, Vaccine Products, Manufacturers, and Event Categories. If data are grouped by any of these items, then the number in the Events Reported column may exceed the total number of unique events. If percentages are shown, then the associated percentage of total unique event reports will exceed 100% in such cases. For example, the number of Symptoms mentioned is likely to exceed the number of events reported, because many reports include more than 1 Symptom. When more than 1 Symptom occurs in a single report, then the percentage of Symptoms to unique events is more than 100%. More information: <http://wonder.cdc.gov/wonder/help/vaers.html#Suppress>.
4. Data contains VAERS reports processed as of 3/26/2021. 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/>