

Mfr Report #	(b) (6)
UF/Importer Report #	
FDA Use Only	

A. PATIENT INFORMATION			
1. Patient Identifier US3912241	2. Age at Time of Event: 59 Years or Date of Birth: (b) (6) -/1960	3. Sex <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight 220.5 lbs or 100.0 kgs
In confidence			
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product Problem (e.g., defects/malfunctions)			
2. Outcomes Attributed to Adverse Event (Check all that apply)			
<input type="checkbox"/> Death: (mm/dd/yyyy) <input type="checkbox"/> Disability or Permanent Damage <input type="checkbox"/> Life-threatening <input type="checkbox"/> Congenital Anomaly/Birth Defect <input checked="" type="checkbox"/> Hospitalization - initial or prolonged <input type="checkbox"/> Other Serious (Important Medical Events) <input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage (Devices)			
3. Date of Event (mm/dd/yyyy) 11/04/2020		4. Date of This Report (mm/dd/yyyy) 11/22/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) PULMONARY EMBOLISM, LLL [Pulmonary embolism]			
Case Description: This 59-year-old, Black, male subject (US3912241) was participating in A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older (mRNA-1273-P301), and experienced pulmonary embolism, LLL (left lower lobe).			
The subject's medical history, as provided by the investigator, included traumatic brain injury 20 years prior, general body aches, current and past exposure to chemicals (pesticides, ammonia, bleach, meat smoking biproducts), current half pack per day smoker, and food allergies to oranges continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 11/04/2020 Angiogram (Continued) #2 11/04/2020 Blood creatinine (continued) #3 11/04/2020 Blood glucose 124 mg/dl High #4 11/04/2020 Blood pressure measurement (continued) #5 11/04/2020 Blood urea (continued) #6 11/04/2020 Body temperature (continued) continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: Black #1 --/--/2000, Current Condition, Pain (Continued) #2 Ongoing, Allergy, Food allergy (Continued) #3 Ongoing, Allergy, Food allergy (Continued) continued in additional info section...			

C. SUSPECT PRODUCT(S)			
1. Name (Give labeled strength & mfr/labeler)			
#1. mRNA-1273 vs Placebo (Code not broken)			
#2.			
2. Dose, Frequency & Route Used		3. Therapy Dates (if unknown, give duration) from/to (or best estimate)	
#1. Blinded, Information withheld.		#1. 10/12/2020 to 10/12/2020	
#2.		#2.	
4. Diagnosis for Use (Indication)		5. Event Abated After Use Stopped or Dose Reduced?	
#1. COVID-19 (Continued)		#1. <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
#2.		#2. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?	
#1. Blinded	#1. Blinded	#1. <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't Apply	
#2.	#2.	#2. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
9. NDC# or Unique ID			
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) 1) ASPIRIN [ACETYLSALICYLIC ACID] (ASPIRIN [ACETYLSALICYLIC ACID]) --/--/2000 to ongoing			
G. ALL MANUFACTURERS			
1. Contact Office (and Manufacturing Site for Devices)		2. Phone Number	
Name ModernaTX, Inc. David Martin MD.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 United States of America		3. Report Source (Check all that apply)	
Email Address		<input type="checkbox"/> Foreign <input checked="" type="checkbox"/> Study <input type="checkbox"/> Literature <input type="checkbox"/> Consumer <input checked="" type="checkbox"/> Health Professional <input type="checkbox"/> User Facility <input type="checkbox"/> Company Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Other:	
4. Date Received by Manufacturer (mm/dd/yyyy) 11/12/2020		5. (A)NDA # IND # 019635 BLA # PMA/ 510(k) # Combination Product <input type="checkbox"/> Yes Pre-1938 <input type="checkbox"/> Yes OTC Product <input type="checkbox"/> Yes	
6. If IND, Give Protocol # mRNA-1273-P301			
7. Type of Report (Check all that apply)			
<input type="checkbox"/> 5-day <input type="checkbox"/> 30-day <input type="checkbox"/> 7-day <input type="checkbox"/> Periodic <input type="checkbox"/> 10-day <input type="checkbox"/> Initial <input type="checkbox"/> 15-day <input checked="" type="checkbox"/> Follow-up #2			
9. Manufacturer Report Number (b) (6)		8. Adverse Event Term(s) Pulmonary embolism	
E. INITIAL REPORTER			
1. Name and Address Dr. Timothy Vachris Synexus - Optimal Research - Austin Austin, Texas UNITED STATES			
Phone # (b) (6)		Email Address (b) (6)	
2. Health Professional? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		3. Occupation Physician	
		4. Initial Reporter Also Sent Report to FDA <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unk	

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event

ADDITIONAL INFORMATION

B5. EVENT DESCRIPTION (Continued)

(itching) and tomatoes (itching). The subject did not have a primary care physician or receive routine medical care. Per medical records, additional medical history included right knee sprain. Concomitant medications reported included acetylsalicylic acid.

The subject received the first dose of blinded intramuscular mRNA-1273 or placebo for SARS-CoV-2 vaccination on 12 Oct 2020.

On 04 Nov 2020, the subject experienced pulmonary embolism, LLL and was hospitalized. The subject reported that he had generalized weakness and chest pain that morning. Several hours later, the symptoms persisted, so he called emergency medical services and was transported to the hospital via ambulance. The subject presented with a two-day history of sharp, pleuritic, left-sided chest pain, improved with lifting of the left arm. He denied fevers, chills, shortness of breath, and cough. The subject was overweight, with a body mass index of 32.6. The review of systems and physical examination were otherwise normal. Vital signs included pulse oximetry 96% on room air, blood pressure 135/79 mmHg, blood pressure mean 97 mmHg, temperature 36.9 degrees Celsius, pulse 91 beats per minute, and respiratory rate 16 breaths per minute. He denied any long car rides or plane rides and was normally a very active person. Laboratory results included prothrombin time 13.6 seconds (11.8-15.2), international normalized ratio 1.01, D-dimer 2.14 ug/ml (less than 0.40), white blood cell count 7.6 K/mm3 (4.8-10.8), red blood cell count 5.47 M/mm3 (4.20-5.40), hemoglobin 14.3 g/dL (14.0-18.0), hematocrit 45.8% (42-52), platelet count 328 K/mm3 (130-400), mean platelet volume 8.7 fL (9.3-12.3), and troponin I 0.01 ng/mL (less than 0.1). A bilateral lower extremity venous color-flow duplex doppler ultrasound was unremarkable with no evidence of deep vein thrombosis. A computed tomography with angiography of the chest showed a segmental pulmonary embolism of the left lower lobe and mild interstitial pulmonary edema. A single-view chest x-ray showed mild cardiogenic pulmonary vascular congestion with no evidence of acute disease. Treatment for the event included subcutaneous enoxaparin sodium and intravenous ketorolac tromethamine for chest pain.

On 05 Nov 2020, the subject was discharged from the hospital. Vital signs prior to discharge included pulse oximetry 94% on room air, blood pressure 146/80 mmHg, temperature 99.3 degrees Fahrenheit, pulse 84 beats per minute, and respiratory rate 16 breaths per minute. Treatment prescribed upon discharge included oral apixaban and oral paracetamol/codeine for chest pain.

Study drug was discontinued in response to the event on 12 Oct 2020.

The event, pulmonary embolism, LLL, was considered unresolved.

The investigator assessed the event, pulmonary embolism, LLL, as related to study drug and not related to study procedure. The Investigator's rationale for assessing the event as related to study drug was due to a temporal association and lack of a clear alternate etiology.

Follow-up received on 12 Nov 2020 and 16 Nov 2020 included updated event term to pulmonary embolism, LLL (previously pulmonary embolism).

Case Comment/Sender's Comment:

This case concerns a 59-year-old, Black, male subject who experienced an unexpected event of pulmonary embolism. The event occurred 24 days after the first, and only dose of blinded study vaccine administration. The event was considered unrelated to the study vaccine in disagreement with the Investigator's assessment, noting the subject's age, high body mass index and status as a current, every day smoker as potential contributing factors.

B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	11/04/2020	Angiogram		
		Showed segmental pulmonary embolism of the left lower lobe and mild interstitial pulmonary edema.		
2	11/04/2020	Blood creatinine	1.1 mg/dl	1.2 0.5
4	11/04/2020	Blood pressure measurement	135/79 mmHg	
5	11/04/2020	Blood urea High	21 mg/dl	20 8
6	11/04/2020	Body temperature	36.9 degree Celsius	

FDA-CBER-2022-1614-4434512

7 11/04/2020 Chest X-ray
Showed mild cardiogenic pulmonary vascular congestion; no evidence of acute disease.

8	11/04/2020	Fibrin D dimer High	2.14 microgram fibrinogen equivalent unit per millilitre	0.40
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9	11/04/2020	Haemoglobin	14.3 g/dL	18.0 14.0
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10	11/04/2020	Heart rate	91 heart beats per minute	
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11	11/04/2020	International normalised ratio	1.01	
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12	11/04/2020	Mean arterial pressure	97 mmHg	
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13	11/04/2020	Mean cell haemoglobin Low	26.1 picogram	33.0 29.0
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14	11/04/2020	Mean cell haemoglobin concentration	31.2 g/dL	36.0 33.0
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15	11/04/2020	Mean platelet volume	8.7 fL	12.3 9.3
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16	11/04/2020	Oxygen saturation	96 percent	
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17	11/04/2020	Platelet count	328 thousand per cubic millimetre	400 130
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18	11/04/2020	Prothrombin time	13.6 Second	15.2 11.8
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19	11/04/2020	Red blood cell count High	5.47 million per cubic millimetre	5.40 4.20
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20	11/04/2020	Respiratory rate	16 breaths per minute	
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21	11/04/2020	Troponin	0.01 ng/mL	0.1
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22	11/04/2020	Ultrasound Doppler Unremarkable with no evidence of deep vein thrombosis.		
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23	11/04/2020	White blood cell count	7.6 thousand per cubic millimetre	10.8 4.8
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B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/2000 Ongoing	Current Condition Pain	ACHES
2	Ongoing	Allergy Food allergy	TO ORANGES- ITCHY ALL OVER
3	Ongoing	Allergy Food allergy	TO TOMATOES- ITCHY ALL OVER

4		Historical Condition Craniocerebral injury	20 years prior
5	Ongoing	Current Condition Tobacco user	For about four years; Unfiltered cigarettes between 3-10 per day.
6		Historical Condition Ligament sprain	Right
7	Ongoing	Current Condition Exposure to household chemicals	Works with ammonia and bleach
8		Historical Condition Environmental exposure	Worked in meat smoker room

C4. DIAGNOSIS FOR USE (Continued)

#1:COVID-19 vaccination (COVID-19 immunisation)