

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

A. PATIENT INFORMATION			
1. Patient Identifier US3272070	2. Age at Time of Event: 74 Years or Date of Birth: (b) (6)/1945	3. Sex <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight ____ lbs or ____ 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 checked="" type="checkbox"/> Death: 10/01/2020 (mm/dd/yyyy) <input type="checkbox"/> Life-threatening <input type="checkbox"/> Hospitalization - initial or prolonged <input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage (Devices)			
<input type="checkbox"/> Disability or Permanent Damage <input type="checkbox"/> Congenital Anomaly/Birth Defect <input type="checkbox"/> Other Serious (Important Medical Events)			
3. Date of Event (mm/dd/yyyy) 10/01/2020		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) MYOCARDIAL INFARCTION [Myocardial infarction]			
Case Description: This 74-year-old, White, male, subject (US3272070) 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 myocardial infarction (MI).			
The subject's medical history, as provided by the investigator, included diabetes mellitus type 2, hypertension, hypercholesterolemia, and chronic obstructive pulmonary disease. Concomitant medications reported included hydrochlorothiazide, amitriptyline, acetylsalicylic acid, colexicaliferol, continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 10/01/2020 Chest X-ray (Continued)			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/2000 to Ongoing, Current Condition, Type 2 diabetes mellitus #2 --/--/2010 to Ongoing, Current Condition, Hypercholesterolaemia #3 --/--/2017 to Ongoing, Current Condition, Hypertension #4 --/--/2020 to Ongoing, Current Condition, Chronic obstructive pulmonary disease			

C. SUSPECT PRODUCT(S)			
1. Name (Give labeled strength & mfr/labeler) (Regimens Continued)			
#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. 08/06/2020 to 08/06/2020	
#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 type="checkbox"/> No <input checked="" 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) HYDROCHLOROTHIAZIDE (HYDROCHLOROTHIAZIDE) --/--/2017 to ongoing continued in additional info section...			
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) 11/04/2020		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 #3			
9. Manufacturer Report Number (b) (6)		8. Adverse Event Term(s) Myocardial infarction	
E. INITIAL REPORTER			
1. Name and Address Dr. Adam Brosz Meridian Clinical Research (Grand Island, Nebraska) 2444 W. Fairley Ave GRAND ISLAND, Nebraska 68803 UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @mcrmed.com	
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)

gabapentin, insulin, losartan, metformin, simvastatin, cyanocobalamin, and empagliflozin.

The subject was allocated to receive intramuscular mRNA-1273 or placebo for SARS-CoV-2 vaccination. The subject received the first dose of blinded study drug on 06 Aug 2020. The subject's last dose of study drug prior to event onset was on 03 Sep 2020.

On 01 Oct 2020, the subject presented via emergency medical services as a cardiac arrest. Chest x-ray was done (results not provided). The subject was treated with rectal acetylsalicylic acid, intravenous propofol, intra-arterial verapamil, intra-arterial nitroglycerin, intravenous sodium chloride 0.9%, intra-arterial heparin, intravenous phenylephrine, intravenous epinephrine, intravenous iopamidol, intravenous norepinephrine, and intravenous vasopressin. That same day, the subject passed away from MI. It was noted by the investigator that the subject had numerous cardiovascular risk factors that precipitated the event which included diabetes mellitus, hypertension, and hyperlipidemia.

Action taken with the study drug was not applicable in response to the event.

The subject died on 01 Oct 2020. The cause of death was reported as MI. It was unknown whether an autopsy was performed.

The investigator assessed the event, MI, as not related to study drug or study procedure.

Follow-up received on 15 OCT 2020 included cause of death confirmation and updated action taken.

Follow-up received on 04 Nov 2020 included clinical course of the event, diagnostic test information, additional medical history and treatment medications.

Case Comment/Sender's Comment:

This case concerns a 74-year-old, male subject with medical history of diabetes mellitus type 2, hypertension and hypercholesterolemia, who experienced an unexpected event of fatal myocardial infarction. The event occurred 29 days after second dose of blinded study medication. The event was considered unrelated to the blinded study medication in agreement with the Investigator's assessment. The event might be explained by the subject's medical history of diabetes mellitus type 2, hypertension and hypercholesterolemia.

B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	10/01/2020	Chest X-ray		
		results not provided		

C4. DIAGNOSIS FOR USE (Continued)

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

C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

- 2) AMITRIPTYLINE (AMITRIPTYLINE) --/--/2010 to ongoing
- 3) ASPIRIN [ACETYLSALICYLIC ACID] (ASPIRIN [ACETYLSALICYLIC ACID]) --/--/1987 to ongoing
- 4) CHOLECALCIFEROL (COLECALCIFEROL) --/--/2010 to ongoing
- 5) GABAPENTIN (GABAPENTIN) --/--/2008 to ongoing
- 6) INSULIN (INSULIN) --/--/2000 to ongoing
- 7) LOSARTAN (LOSARTAN) --/--/2018 to ongoing
- 8) METFORMIN (METFORMIN) --/--/1987 to ongoing
- 9) SIMVASTATIN (SIMVASTATIN) --/--/2010 to ongoing
- 10) CYANOCOBALAMIN (CYANOCOBALAMIN) --/--/2010 to ongoing
- 11) EMPAGLIFLOZIN (EMPAGLIFLOZIN) --/--/2019 to ongoing

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Suspect Product	2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration)	6. Lot #	7. Exp. date
#1 mRNA-1273 vs Placebo Regimen # 2	Blinded, Information withheld.	09/03/2020 to 09/03/2020	Blinded	Blinded