

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

A. PATIENT INFORMATION			
1. Patient Identifier US2021031	2. Age at Time of Event: 72 Years or Date of Birth: (b) (6)/1947	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 type="checkbox"/> Death: _____ (mm/dd/yyyy)			
<input type="checkbox"/> Life-threatening			
<input checked="" 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) 07/28/2020		4. Date of This Report (mm/dd/yyyy) 12/07/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) Struck by lightning [Struck by lightning]			
Case Description: This 72-year-old, White, male subject (US2021031) was participating in A Phase 2a, Randomized, Observer-Blind, Placebo-Controlled, Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older (mRNA-1273-P201) and was struck by lightning.			
The subject's medical history, as provided by the investigator, included seafood allergy, fish allergy, hyperlipidemia, depression, anxiety, and low testosterone. Concomitant medications reported included simvastatin, buspirone hydrochloride, sertraline, and testosterone. continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 07/28/2020 Electrocardiogram (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 --/--/1966 to Ongoing, Allergy, Food allergy #2 --/--/1966 to Ongoing, Allergy, Food allergy #3 --/--/1976 to Ongoing Current Condition, (Continued) continued in additional info section...			

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. 06/01/2020 to 06/01/2020	
#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) SIMVASTATIN (SIMVASTATIN) --/--/1976 to ongoing			
2) BUSPAR (BUSPIRONE HYDROCHLORIDE) --/--/1985			
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) 12/01/2020		5. (A) NDA # _____	
6. If IND, Give Protocol # mRNA-1273-P201		IND # 019635	
7. Type of Report (Check all that apply)		BLA # _____	
<input type="checkbox"/> 5-day <input type="checkbox"/> 30-day		PMA/ 510(k) # _____	
<input type="checkbox"/> 7-day <input type="checkbox"/> Periodic		Combination Product <input type="checkbox"/> Yes	
<input type="checkbox"/> 10-day <input type="checkbox"/> Initial		Pre-1938 <input type="checkbox"/> Yes	
<input type="checkbox"/> 15-day <input checked="" type="checkbox"/> Follow-up #2		OTC Product <input type="checkbox"/> Yes	
9. Manufacturer Report Number (b) (6)		8. Adverse Event Term(s) Struck by lightning	
E. INITIAL REPORTER			
1. Name and Address continued in additional info section			
Dr. Paul Bradley Meridian Clinical Research 340 Eisenhower Dr, Suite 1200 Savannah, Georgia 31406 UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @mcrmed.com	
2. Health Professional?		3. Occupation	
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		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)

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 01 Jun 2020. The subject's last dose of study drug prior to event onset was on 29 Jun 2020.

On 28 Jul 2020, the subject experienced an arrhythmia due to being struck by lightning. He reported that he was (b) (6) and there were storms and bad weather. He remembered a large bright flash of light and suddenly felt dazed and disoriented. He called emergency medical services and was transported to the hospital. He stated that he was told he was having an arrhythmia, but unsure of the abnormal heart rhythm. An electrocardiogram was performed. No treatment information was reported by the investigator.

On 30 Jul 2020, the subject was discharged from the hospital.

Study drug dosing was not applicable as the subject had already received both scheduled doses.

The event, struck by lightning, was considered resolved on 30 Jul 2020.

The investigator assessed the event, struck by lightning, as not related to study drug and not related to study procedure.

Follow-up information received on 01 Dec 2020 and 03 Dec 2020 included updated event term (previously arrhythmia) and date of diagnostic test.

Case Comment/Sender's Comment:

Company Comment: This case concerns a 72-year-old, White, male subject with medical history of hyperlipidemia, recently struck by lightning who experienced an unexpected event of arrhythmia. The event occurred 1 month 26 days after the first dose of blinded study vaccine administration and 28 days after the last dose administration. The event was considered unrelated to the study vaccine in agreement with the Investigator's assessment.

B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	07/28/2020	Electrocardiogram		
		Results pending.		

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
3	--/--/1976 Ongoing	Current Condition Hyperlipidaemia	
4	--/--/1985 Ongoing	Current Condition Depression	
5	--/--/1985 Ongoing	Current Condition Anxiety	
6	--/--/2015 Ongoing	Current Condition Blood testosterone decreased	

C4. DIAGNOSIS FOR USE (Continued)

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

C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

FDA-CBER-2022-1614-4434545

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to ongoing

3) SERTRALINE (SERTRALINE) --/--/1985 to ongoing

4) TESTOSTERONE (TESTOSTERONE) --/--/2015 to ongoing

E1. NAME AND ADDRESS (Continued)

Dr. Paul Bradley

Meridian Clinical Research

340 Eisenhower Dr, Suite 1200 Savannah, Georgia 31406 UNITED STATES

Fax: pbradley@mcrmed.com

Block C - Additional Dosage Regimens

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.	06/29/2020 to 06/29/2020	Blinded	Blinded