

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

<b>A. PATIENT INFORMATION</b>			
1. Patient Identifier US3342256	2. Age at Time of Event: 43 Years or Date of Birth: (b) (6)/1977	3. Sex <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight ____ lbs or ____ kgs
In confidence			
<b>B. ADVERSE EVENT OR PRODUCT PROBLEM</b>			
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: 09/20/2020 (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) 09/20/2020		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) CARDIOPULMONARY ARREST [Cardiopulmonary arrest]			
Case Description: This 43-year-old, male subject (US3342256) 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 cardiopulmonary arrest.			
The subject's medical history, as provided by the investigator, included heart disease, diverticulosis, gastric sleeve surgery, headaches, tooth extraction and tooth infection. Concomitant medications reported included ibuprofen.			
continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: Unknown #1 --/--/2007 to Ongoing, Current Condition, Headache #2 --/--/2010 to Ongoing, Current Condition, Diverticulum #3 05/--/2014 to 05/--/2014, Procedure, Gastrectomy (surgery) continued in additional info section...			

<b>C. SUSPECT PRODUCT(S)</b>			
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. 09/14/2020 to 09/14/2020	
#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) ADVIL [IBUPROFEN] (IBUPROFEN) --/--/2000 to ongoing			
<b>G. ALL MANUFACTURERS</b>			
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) 11/19/2020		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) Cardiopulmonary arrest	
<b>E. INITIAL REPORTER</b>			
1. Name and Address Dr Paul Pickrell Tekton Research Inc Austin, Texas UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @tektonresearch.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

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## 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 14 Sep 2020. The subject's last dose of study drug prior to event onset was on 14 Sep 2020.

On 20 Sep 2020, the subject experienced cardiopulmonary arrest.

On 08 Oct 2020, subject's spouse called the site to inform site staff of the subject's passing; she stated that the subject had a history of heart disease.

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

The subject died on 20 Sep 2020. The cause of death was reported as cardiopulmonary arrest.

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

Follow-up received on 27 Oct 2020 included updated reported event term to cardiopulmonary arrest (previously suspected cardiopulmonary arrest due to acute myocardial infarction).

Follow-up received on 10 Nov 2020 included no new information.

### Case Comment/Sender's Comment:

This case concerns a 43 year old male subject who experienced an unexpected event of suspected cardiopulmonary arrest. The event occurred 6 days after the first dose of the blinded study medication. The event was considered unrelated to the blinded study medication, in agreement with the Investigator's causality assessment. The event might be explained by the subject's medical history of heart disease as a risk factor. Additional information has been requested.

### B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
4	06/--/2020 07/--/2020	Historical Condition Tooth infection	
5	07/--/2020 07/--/2020	Procedure Tooth extraction	
6	Ongoing	Current Condition Cardiac disorder	

### C4. DIAGNOSIS FOR USE (Continued)

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