

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

A. PATIENT INFORMATION			
1. Patient Identifier US3872318	2. Age at Time of Event: 62 Years or Date of Birth: (b) (6)/1958	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: 09/16/2020 (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) 09/16/2020		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) SUICIDE [Suicide]			
Case Description: This 62-year-old, White, male subject (US3872318) 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 committed suicide.			
The subject's medical history, as provided by the investigator included suicidal thoughts in response to separation from his wife, depression, constipation, umbilical hernia, allergy to dogs, left rotator cuff repair, umbilical hernia repair. Concomitant medications reported included 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: White #1 --/--/1976 to --/--/1976 Procedure, (Continued) #2 --/--/1976 to --/--/1976 Historical Condition, (Continued) #3 --/--/2010 to Ongoing 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. 08/27/2020 to 08/27/2020	
#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) BENADRYL /00000402/ (DIPHENHYDRAMINE HYDROCHLORIDE) --/--/2010 to 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) 10/22/2020		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 #4			
9. Manufacturer Report Number (b) (6)		8. Adverse Event Term(s) Suicide	
E. INITIAL REPORTER			
1. Name and Address Dr Michael Levin Clinical Research Center of Nevada LAS VEGAS, Nevada UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @crrcnv.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)

diphenhydramine hydrochloride.

The subject was allocated to receive mRNA-1273 or placebo for SARS-CoV-2 vaccination. The subject received the first dose of blinded study drug on 27 Aug 2020. The subject's last dose of study drug prior to event onset was on 27 Aug 2020.

On 20 Aug 2020, per subject's son, the subject complained of stomach pain, constipation, and diarrhea.

On 16 Sep 2020, the subject's son contacted the site and indicated that his father had committed suicide. The subject seemed to have an obsessive concern about cancer and was convinced that a recent episode of constipation requiring an emergency room evaluation was due to cancer and was relieved to know that it was not. He was prescribed bisacodyl suppositories and oral polyethylene glycol/ electrolytes and the subject's son suspected that his father may have purchased diet pills prior to his death, which both contained caffeine. He also believed that his father suffered from depression and may have thought about suicide before.

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

The subject died on 16 Sep 2020. The cause of death was reported as suicide. An autopsy was not performed.

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

Follow-up received on 23 Sep 2020 and 25 Sep 2020 included unbinding requested information, updated medical history, concomitant medications, and subject demographics.

Follow-up received on 16 Oct 2020 included updated medical history and updated action taken.

Follow-up received on 22 Oct 2020 and 23 Oct 2020 included updated medical history and event details.

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

Case Comment/Sender's Comment:

This case concerns a 62-year-old male subject with a medical history of depression, and suicidal thoughts in response to separation from his wife, who experienced an unexpected event of suicide. The event occurred 20 days after blinded study medication administration. 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 depression and suicidal thoughts.

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1976 --/--/1976	Procedure Rotator cuff repair	Left
2	--/--/1976 --/--/1976	Historical Condition Rotator cuff syndrome	
3	--/--/2010 Ongoing	Allergy Allergy to animal	
4	--/--/2017 Ongoing	Current Condition Umbilical hernia	
5	--/--/2017 --/--/2017	Procedure Umbilical hernia repair	

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6	08/22/2020 Ongoing	Current Condition Constipation	
7	Ongoing	Current Condition Depression	
8	Ongoing	Current Condition Suicidal behaviour	in response to separation from his wife

C4. DIAGNOSIS FOR USE (Continued)

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

C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

ongoing