

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

A. PATIENT INFORMATION			
1. Patient Identifier US3962094	2. Age at Time of Event: 56 Years or Date of Birth: (b) (6)/1964	3. Sex <input checked="" type="checkbox"/> Female <input 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: 10/15/2020 (mm/dd/yyyy) <input type="checkbox"/> Disability or Permanent Damage <input type="checkbox"/> Life-threatening <input type="checkbox"/> Congenital Anomaly/Birth Defect <input 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) 10/15/2020		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) HEAD TRAUMA [Head injury]			
Case Description: This 56-year-old, White, female subject (US3962094) 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 head trauma.			
The subject's medical history, as provided by the investigator, included osteoarthritis of the back, shoulder and knees, capsicum allergy, bilateral carpal tunnel syndrome, uterine cancer, herniated disc, seasonal allergies, ovarian cancer, chronic knee pain, chronic shoulder pain, hysterectomy, 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 --/--/1970 to Ongoing Allergy, (Continued) #2 --/--/1970 to Ongoing Allergy, (Continued) #3 --/--/1982 to Ongoing Current Condition, (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. 09/09/2020 to 09/09/2020	
#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) IRON (IRON) --/--/2010 to ongoing			
2) PRAVASTATIN (PRAVASTATIN) --/--/2019 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) 11/09/2020	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) Head injury		
E. INITIAL REPORTER			
1. Name and Address Dr Paul Nugent Synexus Clinical Research US, Inc. Cincinnati, Ohio UNITED STATES			
Phone # (b) (6)	Email Address (b) (6) @synexus-us.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)

pine tar allergy, high cholesterol, chronic back pain, muscle spasms, water retention, hypertension, leg spasms and glaucoma both eyes. Concomitant medications reported included iron, pravastatin, cholecalciferol, latanoprost, pseudoephedrine hydrochloride, St. John's Wort, fish oil, gabapentin, diclofenac, hydrochlorothiazide, methocarbamol, lisinopril, potassium chloride, hydrocodone and multivitamins NOS.

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 09 Sep 2020. The subject's last dose of study drug prior to event onset was on 09 Sep 2020.

On 12 Oct 2020, the site contacted the subject's sister (emergency contact) after several unsuccessful attempts were made via telephone, email and certified letter to reach the subject.

On 14 Oct 2020, the subject's sister contacted the police for a wellness check for the subject.

On 15 Oct 2020, the site received a voice mail message that stated the subject had passed away and no autopsy was done. The police found the subject deceased on the bathroom floor and reported the subject had head trauma from a fall. No contributing/preexisting factors were reported for the event other than prior medical history.

There was no action taken with the study drug in response to the event.

The subject died on 15 Oct 2020. The cause of death was reported as head trauma.

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

Follow-up received on 09 Nov 2020 included updated event term (previously head trauma due to fall), autopsy, and details of contributing factors.

Case Comment/Sender's Comment:

Company Comment: This case concerns a 56-year-old, White, female subject who experienced an unexpected fatal event of head trauma. The event occurred 1 month 7 days after the first dose of blinded study vaccine administration. The event was considered unrelated to the study vaccine in agreement with the Investigator's assessment. Contributing factor of subject fall.

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1970 Ongoing	Allergy Drug hypersensitivity	Capsicum
2	--/--/1970 Ongoing	Allergy Hypersensitivity	Pine Tar
3	--/--/1982 Ongoing	Current Condition Seasonal allergy	
4	--/--/1995 Ongoing	Current Condition Glaucoma	
5	--/--/1998 Ongoing	Current Condition Fluid retention	
6	--/--/2000 Ongoing	Current Condition Muscle spasms	

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7	--/--/2012 Ongoing	Current Condition Carpal tunnel syndrome	Bilateral
8	--/--/2013 --/--/2013	Historical Condition Uterine cancer	
9	--/--/2013 --/--/2013	Historical Condition Ovarian cancer	
10	--/--/2013 Ongoing	Current Condition Arthralgia	Chronic
11	--/--/2013 Ongoing	Current Condition Arthralgia	Chronic
12	--/--/2013 --/--/2013	Procedure Hysterectomy	
13	--/--/2013 Ongoing	Current Condition Back pain	Chronic
14	--/--/2015 Ongoing	Current Condition Osteoarthritis	
15	--/--/2015 --/--/2015	Historical Condition Intervertebral disc protrusion	
16	--/--/2015 Ongoing	Current Condition Hypertension	
17	--/--/2015 Ongoing	Current Condition Muscle spasms	
18	--/--/2015 Ongoing	Current Condition Spinal osteoarthritis	
19	--/--/2015 Ongoing	Current Condition Osteoarthritis	
20	--/--/2019 Ongoing	Current Condition Blood cholesterol increased	

C4. DIAGNOSIS FOR USE (Continued)

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

C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

3) VITAMIN D3 (COLECALCIFEROL) --/--/2010 to ongoing

4) LATANOPROST (LATANOPROST) --/--/1995 to ongoing

5) PSEUDOEPHEDRINE HYDROCHLORIDE (PSEUDOEPHEDRINE HYDROCHLORIDE) --/--/1982 to ongoing

6) ST JOHN'S WORT (ST JOHN'S WORT) --/--/1997 to ongoing

7) FISH OIL (FISH OIL) 09/12/2020 to ongoing

8) GABAPENTIN (GABAPENTIN) --/--/2014 to ongoing

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- 9) DICLOFENAC (DICLOFENAC) --/--/2000 to ongoing
10) HYDROCHLOROTHIAZIDE (HYDROCHLOROTHIAZIDE) --/--/1998 to ongoing
11) METHOCARBAMOL (METHOCARBAMOL) --/--/2018 to ongoing
12) LISINOPRIL (LISINOPRIL) --/--/2015 to ongoing
13) Klor-Con (POTASSIUM CHLORIDE) --/--/2015 to ongoing
14) HYDROCODONE (HYDROCODONE) --/--/2013 to ongoing
15) MULTIVITAMINS [VITAMINS NOS] (MULTIVITAMINS [VITAMINS NOS]) --/--/1990 to ongoing