

**MEDWATCH**

3500A Facsimile

For use by user-facilities,  
importers, distributors and manufacturers  
for MANDATORY reporting

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

Page 1 of 4

A. PATIENT INFORMATION			
1. Patient Identifier US3142100	2. Age at Time of Event: 69 Years or Date of Birth: (b) (6)/1951	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"/> 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) 09/21/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) COVID-19 [COVID-19]  Case Description: This 69-year-old, White, male subject (US3142100) 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 the non-serious adverse event of COVID-19.  The subject's medical history, as provided by the investigator, included migraines, bilateral nearsighted, hypertension, deep vein thrombosis, pulmonary embolism, intermittent herpes simplex (cold sores), bilateral astigmatism, chronic dry eyes, corrective lens wearer, tonsillitis, dental continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 09/23/2020 Blood pressure measurement (continued) #2 10/20/2020 Blood pressure measurement (continued) #3 09/23/2020 Body temperature 98.9 °F #4 10/05/2020 Body temperature 101.0 °F #5 10/20/2020 Body temperature 97.6 °F #6 09/23/2020 Heart rate (continued) continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/1957 to --/--/1957 Historical Condition, (Continued) #2 --/--/1962 to Ongoing Current Condition, (Continued) #3 --/--/1962 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. 08/04/2020 to 08/04/2020	
#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) AMLODIPINE (AMLODIPINE) --/--/2015 to ongoing 2) ATORVASTATIN (ATORVASTATIN) --/--/2018 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 Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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 type="checkbox"/> Follow-up # _____			
9. Manufacturer Report Number (b) (6)		8. Adverse Event Term(s) COVID-19	
E. INITIAL REPORTER			
1. Name and Address Dr Ripley Hollister Lynn Institute of The Rockies 4190 East Woodmen Road Suite 210 Colorado Springs, Colorado 80920 UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @lhsi.net	
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)

implant, hypercholesterolemia, vitamin D deficiency, and gout. Concomitant medications reported included amlodipine, atorvastatin, allopurinol, ciclosporin, vitamin D, and acetylsalicylic acid.

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 04 Aug 2020. The subject's last dose of study drug prior to event onset was on 03 Sep 2020.

On 21 Sep 2020, the subject began having mild symptoms late in the day after his spouse had received a positive COVID-19 test from another facility.

On 23 Sep 2020, the subject was seen onsite for COVID-19 confirmation testing. A nasopharyngeal rapid polymerase chain reaction for SARS-CoV-2 performed was positive. The subject experienced mild cough, mild shortness of breath, mild difficulty breathing, mild muscle aches (myalgia), mild body aches, mild headache, and mild nasal congestion. The subject's oxygen saturation was 93%, temperature was 98.9 degrees Fahrenheit, pulse 86 beats per minute, respiratory rate 14 breaths per minute, and blood pressure 115/88 mmHg.

On 24 Sep 2020, the subject experienced mild fatigue.

On 25 Sep 2020, the subject experienced the new symptom of mild body aches.

On 27 Sep 2020, the subject started oral ibuprofen for fever.

On 28 Sep 2020, the subject experienced the new symptom of runny nose.

On 05 Oct 2020, treatment included oral acetaminophen for fever of 101 degrees Fahrenheit. The subject did not visit any other medical facility outside of the research site while experiencing COVID-19.

On 14 Oct 2020, his vitals included oxygen saturation at 93%.

On 20 Oct 2020, his body temperature was 97.6 degrees Fahrenheit, pulse 77 beats per minute, respiratory rate 10 breaths per minute, and blood pressure 124/83 mmHg.

Action taken with study drug was not applicable as the subject had already received both scheduled doses.

The event, COVID-19, was reported as not resolved.

The investigator assessed the event, COVID-19, as not related to study drug or study procedure.

Follow-up received on 14 Oct 2020 included updated medical history, vitals, and symptoms.

Follow-up received on 19 Oct 2020 included updated action taken.

Follow-up received on 22 Oct 2020 included treatment medications, vital signs and diagnostic test results.

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

### Case Comment/Sender's Comment:

This case concerns a 69-year-old, male subject who experienced an unexpected event of symptomatic COVID-19. The event occurred 19 days after second dose of blinded study medication administration. The event was considered unrelated to the blinded study medication, in agreement with the Investigator's causality assessment.

### B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	09/23/2020	Blood pressure measurement	115/88 mmHg	
2	10/20/2020	Blood pressure measurement	124/83 mmHg	
6	09/23/2020	Heart rate	86 heart beats per	

FDA-CBER-2022-1614-4433505

minute

7	10/20/2020	Heart rate	77 heart beats per minute
8	09/23/2020	Oxygen saturation	93 percent
9	10/05/2020	Oxygen saturation	90 percent
10	10/14/2020	Oxygen saturation	93 percent
11	09/23/2020	Respiratory rate	14 breaths per minute
12	10/20/2020	Respiratory rate	10 breaths per minute
13	09/23/2020	SARS-CoV-2 antibody test	Blood sample taken for immunologic assessment of SARS-COV-2 infection results pending.
14	09/23/2020	SARS-CoV-2 test Positive Nasopharyngeal swab	

## B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1957 --/--/1957	Historical Condition Tonsillitis	
2	--/--/1962 Ongoing	Current Condition Myopia	Bilateral
3	--/--/1962 Ongoing	Current Condition Corrective lens user	
4	--/--/1966 Ongoing	Current Condition Herpes simplex	Intermittent (cold sores)
5	--/--/1967 --/--/1967	Historical Condition Migraine	
6	--/--/2015 Ongoing	Current Condition Hypertension	
7	--/--/2017 Ongoing	Current Condition Dry eye	Chronic
8	--/--/2017 Ongoing	Current Condition Gout	
9	--/--/2018 --/--/2018	Historical Condition Deep vein thrombosis	
10	--/--/2018 --/--/2018	Historical Condition Pulmonary embolism	

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

11	--/--/2018 Ongoing	Current Condition Astigmatism	Bilateral
12	--/--/2018 Ongoing	Current Condition Hypercholesterolaemia	
13	03/--/2019 Ongoing	Current Condition Vitamin D deficiency	
14	04/--/2020 Ongoing	Current Condition Dental prosthesis user	

#### C4. DIAGNOSIS FOR USE (Continued)

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

#### C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

ongoing

3) ALLOPURINOL (ALLOPURINOL) --/--/2018 to ongoing

4) RESTASIS (CICLOSPORIN) --/--/2018 to ongoing

5) VITAMIN D /07503901/ (VITAMIN D

/07503901/) --/--/2019 to ongoing

6) ASPIRIN /00002701/ (ASPIRIN

/00002701/) --/--/2010 to ongoing

#### 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.	09/03/2020 to 09/03/2020	Blinded	Blinded

**MEDWATCH**

3500A Facsimile

For use by user-facilities,  
importers, distributors and manufacturers  
for MANDATORY reporting

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

Page 1 of 3

A. PATIENT INFORMATION			
1. Patient Identifier US3332001	2. Age at Time of Event: 68 Years or Date of Birth: (b) (6)/1951	3. Sex <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight 145.0 lbs or 65.8 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"/> 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) 09/30/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) COVID-19 [COVID-19]  Case Description: This 68-year-old, White, male subject (US3332001) 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 the non-serious event of COVID-19.  The subject's medical history, as provided by the investigator, included thyroid cancer, sleep apnea, low testosterone, facial and bilateral upper extremities actinic keratosis, thyroid removal, acquired hypothyroidism, alcoholism, insomnia, and hypertension. Concomitant medications reported continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 09/30/2020 Blood pressure measurement (continued) #2 09/30/2020 Body temperature 98.7 °F #3 10/02/2020 Body temperature 97.6 °F #4 09/30/2020 Heart rate (continued) #5 10/02/2020 Oxygen saturation 96 percent #6 09/30/2020 Respiratory rate (continued) continued in additional info section...			
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 Current Condition, (Continued) #2 --/--/2000 to --/--/2000 Historical Condition, (Continued) #3 --/--/2000 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. 08/03/2020 to 08/03/2020	
#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) ENALAPRIL MALEATE (ENALAPRIL MALEATE) 07/07/2019 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 Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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 type="checkbox"/> Follow-up #		
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) COVID-19		
E. INITIAL REPORTER			
1. Name and Address Dr. JAMES PETERSON Foothill Family Clinic - North Salt Lake City, Utah UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @jlewisresearch.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)

included enalapril maleate, trazodone, levothyroxine sodium, alprazolam, alprostadil/ papaverine/ phentolamine, testosterone, diclofenac sodium, and ibuprofen.

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 03 Aug 2020. The subject's last dose of study drug prior to event onset was on 28 Aug 2020.

On 30 Sep 2020, the subject experienced COVID-19 with a positive SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab. Risk factor included his nephew was suspected of exposure. Vital signs included temperature 98.7 degrees Fahrenheit, pulse 98 beats/min, respiratory rate 16 breaths/min, and blood pressure 88/61 mmHg. He took no medications and had no interventions.

On 01 Oct 2020, the subject experienced symptoms of COVID-19 including mild muscle aches.

On 02 Oct 2020, vital signs included oxygen saturation 96% and temperature 97.6 degrees Fahrenheit.

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

The event, COVID-19, was considered resolved on 02 Oct 2020.

The investigator assessed the event, COVID-19, as not related to study drug or study procedure.

Follow-up received on 13 Oct 2020 include updated event term (previously symptomatic COVID-19), vital signs, symptoms, and severity.

Follow-up received on 16 Oct 2020 included updated start date, outcome, end date, symptoms, vital signs, and concomitant medications.

Follow-up received on 22 Oct 2020 included treatment details, updated concomitant medication, and COVID-19 risk factors.

### Case Comment/Sender's Comment:

This case concerns a 68-year-old, White, male subject who experienced the non-serious event of COVID-19. The event happened a month after the second dose of IP. Action taken with IP as well as dechallenge and rechallenge were considered non-applicable. The event is considered unrelated to IP in agreement with the Investigator.

### B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	09/30/2020	Blood pressure measurement	88/61 mmHg	
4	09/30/2020	Heart rate	98 heart beats per minute	
6	09/30/2020	Respiratory rate	16 breaths per minute	
7	09/30/2020	SARS-CoV-2 test Positive Nasopharyngeal swab		

### B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1970 Ongoing	Current Condition Alcoholism	

2	--/--/2000 --/--/2000	Historical Condition Thyroid cancer	
3	--/--/2000 Ongoing	Current Condition Actinic keratosis	Facial and Bilateral Upper Extremities
4	--/--/2000 --/--/2000	Procedure Thyroidectomy	
5	--/--/2000 Ongoing	Current Condition Hypothyroidism	
6	11/29/2017 Ongoing	Current Condition Blood testosterone decreased	
7	--/--/2018 Ongoing	Current Condition Insomnia	
8	--/--/2018 Ongoing	Current Condition Hypertension	
9	10/31/2018 Ongoing	Current Condition Sleep apnoea syndrome	

## C4. DIAGNOSIS FOR USE (Continued)

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

## C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

- 2) TRAZODONE (TRAZODONE) 11/26/2018 to ongoing
- 3) LEVOTHYROXINE SODIUM (LEVOTHYROXINE SODIUM) --/--/2000 to ongoing
- 4) XANAX (ALPRAZOLAM) 11/26/2018 to ongoing
- 5) TRIMIX [ALPROSTADIL;PAPAVERINE;PHENTOLAMINE] (ALPROSTADIL, PAPAVERINE, PHENTOLAMINE) --/--/2017 to ongoing
- 6) TESTOSTERONE (TESTOSTERONE) --/--/2017 to ongoing
- 7) DICLOFENAC SODIUM (DICLOFENAC SODIUM) --/--/2000 to ongoing
- 8) IBUPROFEN (IBUPROFEN) 09/29/2020 to 09/29/2020

## 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.	08/28/2020 to 08/28/2020	Blinded	Blinded



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

<b>A. PATIENT INFORMATION</b>			
1. Patient Identifier US3402029	2. Age at Time of Event: 34 Years or Date of Birth: (b) (6)/1986	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 322.0 lbs or 146.0 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 type="checkbox"/> Death: (mm/dd/yyyy) <input type="checkbox"/> Disability or Permanent Damage			
<input type="checkbox"/> Life-threatening <input type="checkbox"/> Congenital Anomaly/Birth Defect			
<input checked="" type="checkbox"/> Hospitalization - initial or prolonged <input checked="" 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) 09/29/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) COVID-19 [COVID-19]  Case Description: This 34-year-old, White, female subject (US3402029) 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 COVID-19.  The subject's medical history, as provided by the investigator, included hypothyroidism, anxiety, obesity and chronic headaches. Concomitant medications reported included levothyroxine, citalopram hydrobromide and escitalopram oxalate. continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 09/30/2020 Blood pressure measurement (continued) #2 09/30/2020 Body temperature 98.1 °F #3 10/01/2020 Body temperature 100.5 °F #4 10/02/2020 Body temperature 101.0 °F #5 10/03/2020 Body temperature 102.0 °F #6 10/04/2020 Body temperature 98.9 °F continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/2004 to Ongoing, Current Condition, Obesity #2 07/--/2004 to Ongoing, Current Condition, Hypothyroidism #3 --/--/2010 to Ongoing, Current Condition, Headache #4 02/--/2016 to Ongoing, Current Condition, Depression			

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event

<b>C. SUSPECT PRODUCT(S)</b>			
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. 07/27/2020 to 07/27/2020	
#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) SYNTHROID (LEVOTHYROXINE SODIUM) 07/--/2004 to ongoing continued in additional info section...			
<b>G. ALL MANUFACTURERS</b>			
1. Contact Office (and Manufacturing Site for Devices)		2. Phone Number	
Name ModernaTX, Inc. David Martin Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<input type="checkbox"/> Foreign	
4. Date Received by Manufacturer (mm/dd/yyyy) 10/28/2020		<input checked="" type="checkbox"/> Study	
6. If IND, Give Protocol # mRNA-1273-P301		<input type="checkbox"/> Literature	
7. Type of Report (Check all that apply)		<input type="checkbox"/> Consumer	
<input type="checkbox"/> 5-day <input type="checkbox"/> 30-day		<input checked="" type="checkbox"/> Health Professional	
<input type="checkbox"/> 7-day <input type="checkbox"/> Periodic		<input type="checkbox"/> User Facility	
<input type="checkbox"/> 10-day <input type="checkbox"/> Initial		<input type="checkbox"/> Company Representative	
<input type="checkbox"/> 15-day <input type="checkbox"/> Follow-up #		<input type="checkbox"/> Distributor	
Combination Product <input type="checkbox"/> Yes		<input type="checkbox"/> Other:	
Pre-1938 <input type="checkbox"/> Yes			
OTC Product <input type="checkbox"/> Yes			
9. Manufacturer Report Number (b) (6)		8. Adverse Event Term(s) COVID-19	
<b>E. INITIAL REPORTER</b>			
1. Name and Address Dr. Frank Eder Meridian Clinical Research, LLC Binghamton, New York 13901 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			



**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 27 Jul 2020. The subject's last dose of study drug prior to event onset was on 24 Aug 2020.

On 29 Sep 2020, the subject experienced COVID-19. The subject was exposed to COVID-19 at place of employment and became symptomatic. The site was notified by subject's friend that her oxygen saturation declined, and she had difficulty breathing.

On 30 Sep 2020, the subject had a positive SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab. The subject experienced symptoms of COVID-19 including mild chills, mild cough, mild fatigue, mild muscle aches, mild headache, mild loss of taste, mild nasal congestion, mild sore throat, nausea, vomiting, and poor appetite. Vital signs included oxygen saturation 98%, temperature 98.1 degrees Fahrenheit, pulse 102 beats/min, respiratory rate 16 breaths/min and blood pressure 121/92 mmHg.

On 01 Oct 2020, the subject experienced the new symptom of mild loss of smell. Vital signs included oxygen saturation 99% and temperature 100.5 degrees Fahrenheit.

On 02 Oct 2020, vital signs included oxygen saturation 97% and temperature 101.0 degrees Fahrenheit.

On 03 Oct 2020, vital signs included oxygen saturation 94% and temperature 102.0 degrees Fahrenheit. Treatment for the event included oral guaifenesin. The subject was taking ibuprofen and paracetamol for fever.

On 04 Oct 2020, the subject experienced the new symptom of mild diarrhea. Vital signs included oxygen saturation 94% and temperature 98.9 degrees Fahrenheit.

On 05 Oct 2020, treatment for the event included oral dexamethasone.

On 06 Oct 2020, the subject felt better.

On 07 Oct 2020, the subject went to the emergency room where she was later admitted to the COVID unit of the hospital. The subject was on apixaban and dexamethasone in outpatient setting. Vital signs included oxygen saturation 88% and temperature 101.0 degrees Fahrenheit. The subject experienced the new symptom of moderate shortness of breath. A chest x-ray showed bibasilar infiltrate. Treatment for the event included oxygen, oral doxycycline, oral remdesivir, and intravenous convalescent plasma.

On 08 Oct 2020, vital signs included oxygen saturation 83% and temperature 101.4 degrees Fahrenheit.

On 09 Oct 2020, vital signs included oxygen saturation 88% and temperature 98.2 degrees Fahrenheit.

On 13 Oct 2020, the subject was examined on the bedside. She was vitally and hemodynamically stable. She had some dry cough without sputum production.

On 13 Oct 2020, the subject was discharged from the hospital.

Action taken with study drug was reported as not applicable in response to the event, as the subject had already received both scheduled doses.

The event, COVID-19, was considered as resolved on 12 Oct 2020.

The investigator assessed the event, COVID-19, as not related to study drug or study procedure.

Follow-up received 07 Oct 2020 included updated serious criteria, treatment medications, hospital admission date, and course of illness.

Follow-up received on 09 Oct 2020 included updated event term to COVID-19 (previously positive SARS2 COVID-19), vital signs, symptoms and action taken.

Follow-up received on 16 Oct 2020 included no new information.

Follow-up received on 18 Oct 2020 included updated event outcome, hospital discharge date, diagnostic testing, vital signs, and symptoms.

Follow-up received on 28 Oct 2020 included updated vital signs, concomitant medication, event severity grade, stop date and outcome.

## Case Comment/Sender's Comment:

This case concerns a 34 year-old, female subject who experienced an unexpected event of positive COVID-19. The event occurred 1 month 6 days after second dose of blinded study medication administration. The event was considered unrelated to the blinded study medication, in agreement with the Investigator's causality assessment.

## B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	09/30/2020	Blood pressure measurement	121/92 mmHg	
7	10/07/2020	Body temperature	101.0 °F	
8	10/08/2020	Body temperature	101.4 °F	
9	10/09/2020	Body temperature	98.2 °F	
10	10/07/2020	Chest X-ray Showed bibasilar infiltrate.		
11	09/30/2020	Heart rate	102 /min	
12	09/30/2020	Oxygen saturation	98 percent	
13	10/01/2020	Oxygen saturation	99 percent	
14	10/02/2020	Oxygen saturation	97 percent	
15	10/03/2020	Oxygen saturation	94 percent	
16	10/04/2020	Oxygen saturation	94 percent	
17	10/07/2020	Oxygen saturation	88 percent	
18	10/08/2020	Oxygen saturation	83 percent	
19	10/09/2020	Oxygen saturation	88 percent	
20	09/30/2020	Respiratory rate	16 breaths per minute	
21	09/30/2020	SARS-CoV-2 test Positive Nasopharyngeal swab		

## C4. DIAGNOSIS FOR USE (Continued)

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

## C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

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

- 2) LEXAPRO (ESCITALOPRAM OXALATE) 02/--/2016 to ongoing
- 3) CELEXA [CITALOPRAM HYDROBROMIDE] (CITALOPRAM HYDROBROMIDE) ongoing

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.	08/24/2020 to 08/24/2020	Blinded	Blinded

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

A. PATIENT INFORMATION			
1. Patient Identifier US3022233	2. Age at Time of Event: 53 Years or Date of Birth: (b) (6) --/1967	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 168.9 lbs or 76.6 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"/> 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) 10/02/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) COVID-19 [COVID-19]			
Case Description: This 53-year-old, Black, female subject (US3022233) 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 vs Placebo) and experienced the non-serious event of COVID-19.			
The subject's medical history, as provided by the investigator, included eczema, monocycline allergy, and bilateral tubal ligation. No relevant concomitant medications were reported.			
continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates			
#1 10/09/2020 Blood pressure measurement (continued)			
#2 10/04/2020 Body temperature 9 °F			
#3 10/08/2020 Body temperature 98.1 °F			
#4 10/09/2020 Body temperature 37.1 °C			
#5 10/10/2020 Body temperature 99.9 °F			
#6 10/11/2020 Body temperature 99.1 °F			
continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: Black			
#1 --/--/2002 to --/--/2002, Procedure, Female sterilisation (Bilateral)			
#2 --/--/2010 to Ongoing, Allergy, Drug hypersensitivity (MONOCYCLINE)			
#3 --/--/2012 to Ongoing, Current Condition, Eczema			

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event

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. 08/20/2020 to 08/20/2020	
#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)			
G. ALL MANUFACTURERS			
1. Contact Office (and Manufacturing Site for Devices)		2. Phone Number	
Name ModernaTX, Inc. David Martin Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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 type="checkbox"/> Follow-up #			
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) COVID-19		
E. INITIAL REPORTER			
1. Name and Address Dr. PAUL BRADLEY Meridian Clinical Research-(Savannah Georgia) SAVANNAH, GA UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @mcrmed.com	
2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA	
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Physician	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unk	

## 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 20 Aug 2020. The subject's last dose of study drug prior to event onset was 24 Sep 2020.

The subject had an occupational risk (educators and students) and location and living circumstances risk (resides in low density, multi-family setting) of exposure for COVID-19.

On 02 Oct 2020, the subject experienced COVID-19 with a positive SARS-CoV-2 by reverse-transcriptase polymerase chain reaction nasopharyngeal swab collected on 09 Oct 2020. The subject was treated with oral naproxen sodium for headache.

On 02 Oct 2020 through 19 Oct 2020, the subject experienced intermittent mild to moderate headache, loss of taste, loss of smell and nausea. The subject denied chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches, body aches, nasal congestion, runny nose, vomiting, diarrhea, and sore throat.

On 09 Oct 2020, vital signs included pulse 79 beats per minute, respiratory rate 15 breaths per minute, blood pressure 114/75 mmHg, oxygen saturation 99%, and temperature 37.1 degrees Celsius.

On 21 Oct 2020, oxygen saturation was 93%.

On 22 Oct 2020, oxygen saturation normalized at 99%.

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

The event, COVID-19, was considered as resolved on 21 Oct 2020.

The investigator assessed the event, COVID-19, as not related to study drug and not related to study procedure.

Follow-up received on 26 Oct 2020 included updated event term (previously COVID infection), risk of exposure, laboratory test, event start date, and action taken with study drug.

Follow-up received on 02 Nov 2020 and 03 Nov 2020 included additional COVID-19 symptom assessments.

Follow-up received on 09 Nov 2020 included updated treatment, symptoms, and event start date.

Follow-up received on 19 Nov 2020 included updated event term (previously COVID-19 infection), lab data, and outcome.

#### Case Comment/Sender's Comment:

Company Comment: This case concerns a 53-year-old, Black, female subject who experienced an unexpected event of COVID-19. The event occurred 1 month 13 days after the first dose of blinded study vaccine administration and 9 days after the last dose administration. The event was considered unrelated to the study vaccine in agreement with the Investigator's assessment. The subject had an occupational risk and location and living circumstances risk of exposure for COVID-19.

### B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	10/09/2020	Blood pressure measurement	114/75 mmHg	
7	10/12/2020	Body temperature	98.3 °F	
8	10/13/2020	Body temperature	97.3 °F	
9	10/14/2020	Body temperature	95.8 °F	
10	10/15/2020	Body temperature	98.1 °F	
11	10/16/2020	Body temperature	96.8 °F	
12	10/17/2020	Body temperature	98.2 °F	

FDA CBER 2022 1614 4433516

13	10/18/2020	Body temperature	98.2 °F
14	10/19/2020	Body temperature	97.6 °F
15	10/20/2020	Body temperature	97.6 °F
16	10/21/2020	Body temperature	97.5 °F
17	10/22/2020	Body temperature	97.5 °F
18	10/09/2020	Heart rate	79 heart beats per minute
19	10/08/2020	Oxygen saturation	98 percent
20	10/09/2020	Oxygen saturation	99 percent
21	10/10/2020	Oxygen saturation	99 percent
22	10/11/2020	Oxygen saturation	98 percent
23	10/12/2020	Oxygen saturation	98 percent
24	10/13/2020	Oxygen saturation	98 percent
25	10/14/2020	Oxygen saturation	99 percent
26	10/15/2020	Oxygen saturation	98 percent
27	10/16/2020	Oxygen saturation	99 percent
28	10/17/2020	Oxygen saturation	99 percent
29	10/18/2020	Oxygen saturation	99 percent
30	10/19/2020	Oxygen saturation	99 percent
31	10/20/2020	Oxygen saturation	98 percent
32	10/21/2020	Oxygen saturation	93 percent
33	10/22/2020	Oxygen saturation	99 percent
34	10/09/2020	Respiratory rate	15 breaths per minute
35	10/13/2020	Respiratory rate	breaths per minute
36	10/09/2020	SARS-CoV-2 test Positive Nasal Swab	

C4. DIAGNOSIS FOR USE (Continued)

FDA-CBER-2022-1614-4433517

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

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

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.	09/24/2020 to 09/24/2020	Blinded	Blinded



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

A. PATIENT INFORMATION			
1. Patient Identifier US3262099	2. Age at Time of Event: 61 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 type="checkbox"/> Death: _____ (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) 10/12/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) SYMPTOMATIC CONFIRMED COVID POSITIVE INFECTION [COVID-19]  Case Description: Cohort: >=18 and <65 years and at risk Date of Birth: 1958 (b) (6)  AE: SYMPTOMATIC CONFIRMED COVID POSITIVE INFECTION Start Date: 20201012 SAE Description: Action Taken: Not Applicable Action Taken ER Visit: 1 Related to procedure: Not Related Severity: Grade 2/Moderate continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 10/13/2020 Body temperature 99.3 °F #2 10/16/2020 Body temperature 98.6 °F #3 10/17/2020 Body temperature 97.6 °F #4 10/18/2020 Body temperature 97.6 °F #5 10/19/2020 Body temperature 97.0 °F #6 10/20/2020 Body temperature 97.1 °F continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/1999 to Ongoing Historical Condition, (Continued) #2 --/--/2015 to Ongoing Historical Condition, (Continued) #3 --/--/2018 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. 08/05/2020 to 08/05/2020	
#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) CONCERTA (METHYLPHENIDATE HYDROCHLORIDE) --/--/1999 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 Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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) 12/03/2020	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 type="checkbox"/> Follow-up # _____		
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) COVID-19		
E. INITIAL REPORTER			
1. Name and Address Dr. ATOYA ADAMS AB Clinical Trials 2121 E. FLAMINGO ROAD LAS VEGAS, NV 89119 UNITED STATES			
Phone # (b) (6)		Email Address (b) (6)	
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)

Study Drug iterations first and closest:  
Study Drug First Start Date: 20200805  
Study Drug First Start Time:  
Study Drug Latest Start Date: 20200903  
Study Drug Latest Start Time:

### Case Comment/Sender's Comment:

This case concerns a 61-year-old white male subject with a medical history of attention deficit hyperactivity disorder, hypertension, chronic intermittent cough and obesity, who experienced the non-serious event of symptomatic confirmed COVID positive infection. The event occurred approximately 5 weeks after last dose of IP. No action taken with IP. Dechallenge and rechallenge were not applicable. Th event was considered unrelated to IP in agreement with the Investigator.

### B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
7	10/21/2020	Body temperature	98.3 °F	
8	10/22/2020	Body temperature	96.4 °F	
9	10/23/2020	Body temperature	97.9 °F	
10	10/24/2020	Body temperature	97.9 °F	
11	10/25/2020	Body temperature	94.5 °F	
12	10/26/2020	Body temperature	97.4 °F	
13	10/27/2020	Body temperature	97.9 °F	
14	10/28/2020	Body temperature	98.5 °F	
15	10/29/2020	Body temperature	97.9 °F	
16	10/30/2020	Body temperature	97.4 °F	
17	10/31/2020	Body temperature	97.8 °F	
18	11/01/2020	Body temperature	98.1 °F	
19	11/02/2020	Body temperature	97.6 °F	
20	11/03/2020	Body temperature	97.1 °F	
21	11/04/2020	Body temperature	98.0 °F	
22	11/05/2020	Body temperature	97.2 °F	
23	11/06/2020	Body temperature	98.1 °F	
24	11/07/2020	Body temperature	97.0 °F	
25	10/16/2020	Oxygen saturation	93 percent	

FDA-CBER-2022-1614-4433520

26	10/17/2020	Oxygen saturation	95 percent
27	10/18/2020	Oxygen saturation	94 percent
28	10/19/2020	Oxygen saturation	96 percent
29	10/20/2020	Oxygen saturation	94 percent
30	10/21/2020	Oxygen saturation	94 percent
31	10/22/2020	Oxygen saturation	94 percent
32	10/23/2020	Oxygen saturation	93 percent
33	10/24/2020	Oxygen saturation	95 percent
34	10/25/2020	Oxygen saturation	96 percent
35	10/26/2020	Oxygen saturation	96 percent
36	10/27/2020	Oxygen saturation	95 percent
37	10/28/2020	Oxygen saturation	96 percent
38	10/29/2020	Oxygen saturation	95 percent
39	10/30/2020	Oxygen saturation	95 percent
40	10/31/2020	Oxygen saturation	96 percent
41	11/01/2020	Oxygen saturation	97 percent
42	11/02/2020	Oxygen saturation	97 percent
43	11/03/2020	Oxygen saturation	96 percent
44	11/04/2020	Oxygen saturation	96 percent
45	11/05/2020	Oxygen saturation	95 percent
46	11/06/2020	Oxygen saturation	96 percent
47	11/07/2020	Oxygen saturation	96 percent
48	10/12/2020	SARS-CoV-2 test Positive Nasopharyngeal swab	

## B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1999 Ongoing	Historical Condition Attention deficit hyperactivity disorder	
2	--/--/2015 Ongoing	Historical Condition Hypertension	
3	--/--/2018 Ongoing	Current Condition Cough	Intermittent
4	--/--/2018 Ongoing	Historical Condition CHRONIC INTERMITTENT COUGH	
5	03/--/2020 Ongoing	Historical Condition Obesity	

#### C4. DIAGNOSIS FOR USE (Continued)

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

#### C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

- 2) AMLODIPINE (AMLODIPINE) --/--/2019 to ongoing
- 3) NEBIVOLOL (NEBIVOLOL) --/--/2015 to ongoing
- 4) LOSARTAN (LOSARTAN) --/--/2015 to ongoing
- 5) METFORMIN (METFORMIN) --/--/2018 to ongoing
- 6) METHYLPREDNISOLONE (METHYLPREDNISOLONE) 10/24/2020 to 10/24/2020
- 7) METHYLPREDNISOLONE (METHYLPREDNISOLONE) 10/25/2020 to 10/25/2020
- 8) METHYLPREDNISOLONE (METHYLPREDNISOLONE) 10/20/2020 to 10/20/2020
- 9) METHYLPREDNISOLONE (METHYLPREDNISOLONE) 10/22/2020 to 10/22/2020
- 10) METHYLPREDNISOLONE (METHYLPREDNISOLONE) 10/23/2020 to 10/23/2020
- 11) CONCERTA-ER --/--/1999 to UNK

#### 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.	09/03/2020 to 09/03/2020	Blinded	Blinded

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

A. PATIENT INFORMATION			
1. Patient Identifier US3752162	2. Age at Time of Event: 70 Years or Date of Birth: (b) (6)/1950	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"/> 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) 10/17/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) COVID-19 INFECTION [COVID-19]  Case Description: This 70-year-old, White, male subject (US3752162) 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 the non-serious event of COVID-19 infection.  The subject's medical history, as provided by the investigator, included colonoscopy (underlying condition unknown), vision disturbance (unknown diagnosis), bilateral cataract surgery, wears glasses (unknown diagnosis), hypertriglyceridemia, asthma, cholecystectomy (associated continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 10/18/2020 Body temperature 100.6 °F #2 10/19/2020 Body temperature 98.3 °F #3 10/18/2020 Oxygen saturation 88 percent #4 10/19/2020 Oxygen saturation 95 percent #5 10/27/2020 SARS-CoV-2 test (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 --/--/1976 to Ongoing Current Condition, (Continued) #2 --/--/1985, Procedure, Colonoscopy (Continued) #3 --/--/1990 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. 08/19/2020 to 08/19/2020	
#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) TAMSULOSIN (TAMSULOSIN) 02/--/2020 to ongoing 2) METHOCARBAMOL (METHOCARBAMOL) 10/15/2020 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 Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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) 11/06/2020		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 type="checkbox"/> Follow-up # _____			
9. Manufacturer Report Number (b) (6)		8. Adverse Event Term(s) COVID-19	
E. INITIAL REPORTER			
1. Name and Address Dr. PRIYANTHA WIJewardane Baptist Health Center for Clinical Research Little Rock, Arkansas UNITED STATES			
Phone # (b) (6)		Email Address (b) (6)	
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)

condition unknown), gastroesophageal reflux disease, skin cancer removal right hand (unknown if benign or malignant), low back pain, vertigo, and enlarged prostate. Concomitant medications reported included tamsulosin, methocarbamol, and hydrocodone.

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 19 Aug 2020. The subject's last dose of study drug prior to event onset was on 16 Sep 2020.

The subject had an occupational risk (healthcare worker) of exposure for COVID-19.

On 13 Oct 2020, the subject had known COVID-19 exposure.

On 17 Oct 2020, the subject experienced COVID-19 infection with a positive SARS-CoV-2 real-time reverse transcription polymerase chain reaction saliva test collected on 27 Oct 2020. Symptoms included moderate cough, moderate fatigue, moderate muscle aches, moderate body aches and moderate headache. Treatment included oral paracetamol.

On 18 Oct 2020, new symptoms included moderate shortness of breath. Vital signs included temperature 100.6 degrees Fahrenheit and oxygen saturation 88%.

On 19 Oct 2020, vital signs included temperature 98.3 degrees Fahrenheit and oxygen saturation 95%.

On 20 Oct 2020, treatment included oral famotidine and oral paracetamol/ diphenhydramine.

On 21 Oct 2020, new symptom included mild runny nose.

On 22 Oct 2020, new symptoms included severe loss of taste and severe loss of smell. Treatment included oral zinc acetate/ zinc gluconate.

On 24 Oct 2020, new symptoms included mild chills and mild diarrhea.

On 28 Oct 2020, treatment included oral colecalciferol and oral ascorbic acid.

On 02 Nov 2020, symptoms had resolved.

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

The event, COVID-19 infection, was reported as resolved on 02 Nov 2020.

The investigator assessed the event, COVID-19 infection, as not related to study drug and not related to study procedure.

Follow-up received on 06 Nov 2020 included updated event term (previously COVID-19 positive), action taken, COVID-19 exposure information and treatment medications.

Case Comment/Sender's Comment:

Company Comment: This case concerns a 70-year-old, White, male subject who experienced an unexpected event of COVID-19 infection. The event occurred 1 month 29 days after the first dose of blinded study vaccine administration and 1 month 2 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
5	10/27/2020	SARS-CoV-2 test Positive Saliva Test		

## B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1976 Ongoing	Current Condition Hypertriglyceridaemia	
2	--/--/1985 --/--/1985	Procedure Colonoscopy	(UNDERLYING CONDITION UNKNOWN)
3	--/--/1990 Ongoing	Current Condition Visual impairment	(UNKNOWN DIAGNOSIS)
4	--/--/1990 Ongoing	Current Condition Corrective lens user	(UNKNOWN DIAGNOSIS)
5	--/--/1990 Ongoing	Current Condition Gastroesophageal reflux disease	
6	--/--/2000 Ongoing	Current Condition Asthma	
7	--/--/2013 --/--/2013	Procedure Cholecystectomy	(ASSOCIATED CONDITION UNKNOWN)
8	--/--/2015 Ongoing	Current Condition Back pain	
9	--/--/2018 --/--/2018	Procedure Cataract operation	BILATERAL
10	--/--/2019 Ongoing	Current Condition Vertigo	
11	--/--/2020 --/--/2020	Procedure Skin neoplasm excision	RIGHT HAND (UNKNOWN IF BENIGN OR MALIGNANT)
12	--/--/2020 Ongoing	Current Condition Prostatomegaly	

## C4. DIAGNOSIS FOR USE (Continued)

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

## C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

10/23/2020

3) HYDROCODONE (HYDROCODONE) 10/15/2020 to 10/23/2020

## Block C - Additional Dosage Regimens

Suspect Product	2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration)	6. Lot #	7. Exp. date
-----------------	---------------------------------	---	----------	--------------



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

#1 mRNA-1273 vs Placebo Blinded, Information withheld. 09/16/2020 to 09/16/2020 Blinded Blinded  
Regimen # 2

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

A. PATIENT INFORMATION			
1. Patient Identifier US3752229	2. Age at Time of Event: 45 Years or Date of Birth: (b) (6)/1975	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 217.0 lbs or 98.4 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"/> 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) 10/23/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) SYMPTOMATIC COVID 19 [COVID-19]			
Case Description: This 45-year-old, Latino, female subject (US3752229) 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 the non-serious event of symptomatic COVID-19.			
The subject's medical history, as provided by the investigator, included headaches, tinnitus, osteoarthritis with back pain, anxiety/panic attacks, anemia, urinary incontinence, insomnia, attention deficit disorder, appendectomy, cesarean continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 10/27/2020 Blood pressure measurement (continued) #2 10/26/2020 Body temperature 101.9 °F #3 10/27/2020 Body temperature 99.3 °F #4 10/28/2020 Body temperature 101.9 °F #5 10/29/2020 Body temperature 102.0 °F #6 10/30/2020 Body temperature 101.2 °F continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: Other #1 --/--/1979 to Ongoing Allergy, (Continued) #2 --/--/1985 to --/--/1985 Procedure, (Continued) #3 --/--/1985 to --/--/1985 Historical 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. 08/24/2020 to 08/24/2020	
#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) AMITRIPTYLINE (AMITRIPTYLINE) 01/--/2020 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 Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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) 11/16/2020	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 type="checkbox"/> Follow-up #		
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) COVID-19		
E. INITIAL REPORTER			
1. Name and Address Dr. PRIYANTHA WIJewardane Baptist Health Center for Clinical Research Little Rock, Arkansas UNITED STATES			
Phone # (b) (6)		Email Address (b) (6)	
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)

section x2, carpal tunnel release right, hypertension, lysis of adhesions laparotomy (unknown associated condition), penicillin allergy, right carpal tunnel syndrome, severe uterine bleeding, obesity, gallstones, appendicitis, hypercholesterolemia, cardiac arrhythmia (unknown type), hyperthyroidism, cholecystectomy (unknown associated condition), gastroesophageal reflux disease, intestinal surgery consisting of lap band procedure, and hysterectomy (unknown associated condition). Concomitant medications reported included amitriptyline, metoprolol, sertraline, hydrochlorothiazide/ olmesartan medoxomil, hydrocodone, metaxalone, gabapentin, and amphetamine aspartate/ amphetamine sulfate/ dexamfetamine saccharate/ dexamfetamine sulfate.

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 24 Aug 2020. The subject's last dose of study drug prior to event onset was on 21 Sep 2020.

On 23 Oct 2020, the subject experienced symptomatic COVID-19 with a positive SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab collected on 27 Oct 2020. Between 23 Oct 2020 and 12 Nov 2020, the subject intermittently experienced mild to severe symptoms of chills, sore throat, headache, cough, fatigue, muscle aches, body aches, nausea, loss of taste and smell, nasal congestion, runny nose and vomiting. During this period the subject did not report any of the following symptoms including diarrhea, shortness of breath and difficult breathing. The subject known exposure risks include working in a healthcare setting with frequent contact with COVID-19 positive patients. However, the subject is always in full personal protection equipment (PPE). The subject spouse and two children were also COVID-19 positive. Treatment included ibuprofen, acetaminophen/ dextromethorphan HBr/doxylamine succinate, acetaminophen/dextromethorphan HBr/phenylephrine HCl, azithromycin and benzonatate.

Between 28 Oct 2020 and 03 Nov 2020, the subject experienced fever ranging from 100.4 to 102.0 degrees Fahrenheit.

On 02 Nov 2020, oxygen saturation 92%.

On 04 Nov 2020, vital signs included oxygen saturation 96% and temperature 98.8 degrees Fahrenheit.

The action taken with the study drug in response to the event was reported as not applicable.

The event, symptomatic COVID-19, was reported as resolved on 12 Nov 2020.

The investigator assessed the event, symptomatic COVID-19, as not related to study drug or study procedure.

Follow-up received on 06 Nov 2020 included updated event term (previously, COVID-19 positive), COVID-19 exposure, action taken, treatment, and symptoms.

Follow-up received on 16 Nov 2020 included updated event term (previously COVID-19 infection), end date and outcome.

#### Case Comment/Sender's Comment:

This case concerns the 45-year-old female subject who experienced an unexpected event of symptomatic COVID 19. The event occurred 1 month 3 days after the second dose of blinded study medication. The event was considered unrelated to the blinded study medication in agreement with the Investigator.

### B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	10/27/2020	Blood pressure measurement	138/82 mmHg	
7	10/31/2020	Body temperature	100.4 °F	
8	11/01/2020	Body temperature	100.4 °F	
9	11/02/2020	Body temperature	102.0 °F	
10	11/03/2020	Body temperature	100.1 °F	
11	11/04/2020	Body temperature	98.8 °F	FDA-CBER-2022-1614-4433528

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

12	11/05/2020	Body temperature	98.4 °F
13	11/06/2020	Body temperature	99.8 °F
14	11/07/2020	Body temperature	97.8 °F
15	11/08/2020	Body temperature	98.6 °F
16	11/09/2020	Body temperature	98.6 °F
17	11/10/2020	Body temperature	98.1 °F
18	11/11/2020	Body temperature	97.7 °F
19	11/12/2020	Body temperature	98.5 °F
20	10/27/2020	Heart rate	81 heart beats per minute
21	11/10/2020	Heart rate	heart beats per minute
22	10/27/2020	Oxygen saturation	99 percent
23	10/28/2020	Oxygen saturation	96 percent
24	10/29/2020	Oxygen saturation	98 percent
25	10/30/2020	Oxygen saturation	96 percent
26	10/31/2020	Oxygen saturation	98 percent
27	11/01/2020	Oxygen saturation	98 percent
28	11/02/2020	Oxygen saturation	92 percent
29	11/03/2020	Oxygen saturation	99 percent
30	11/04/2020	Oxygen saturation	96 percent
31	11/05/2020	Oxygen saturation	98 percent
32	11/06/2020	Oxygen saturation	98 percent
33	11/07/2020	Oxygen saturation	98 percent
34	11/08/2020	Oxygen saturation	100 percent
35	11/09/2020	Oxygen saturation	100 percent
36	11/10/2020	Oxygen saturation	100 percent
37	11/11/2020	Oxygen saturation	100 percent
38	11/12/2020	Oxygen saturation	98 percent

FDA-CBER-2022-1614-4433529

39	10/27/2020	Respiratory rate	16 breaths per minute
----	------------	------------------	-----------------------

40	10/27/2020	SARS-CoV-2 test Positive Nasopharyngeal swab
----	------------	--

## B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1979 Ongoing	Allergy Drug hypersensitivity	
2	--/--/1985 --/--/1985	Procedure Appendectomy	
3	--/--/1985 --/--/1985	Historical Condition Appendicitis	
4	--/--/1990 Ongoing	Current Condition Headache	
5	--/--/2000 --/--/2000	Procedure Caesarean section	
6	--/--/2000 --/--/2000	Historical Condition Cholelithiasis	
7	--/--/2000 --/--/2000	Procedure Cholecystectomy	(UNKNOWN ASSOCIATED CONDITION)
8	--/--/2002 Ongoing	Current Condition Anxiety	PANIC ATTACKS
9	--/--/2002 Ongoing	Current Condition Panic attack	ANXIETY
10	--/--/2003 UNK	Historical Condition Hyperthyroidism	
11	--/--/2004 --/--/2004	Historical Condition Obesity	
12	--/--/2004 --/--/2004	Procedure Gastrointestinal surgery	CONSISTING OF LAP BAND PROCEDURE
13	--/--/2005 --/--/2005	Procedure Caesarean section	
14	--/--/2005 Ongoing	Current Condition Hypertension	

15	07/--/2006 Ongoing	Current Condition Osteoarthritis	BACK PAIN
16	07/--/2006 Ongoing	Current Condition Back pain	OSTEOARTHRITIS
17	--/--/2010 Ongoing	Current Condition Anaemia	
18	--/--/2010 Ongoing	Current Condition Hypercholesterolaemia	
19	--/--/2013 Ongoing	Current Condition Urinary incontinence	
20	--/--/2013 --/--/2013	Procedure Carpal tunnel decompression	right
21	--/--/2013 --/--/2013	Historical Condition Carpal tunnel syndrome	(R)
22	--/--/2013 --/--/2013	Historical Condition Uterine haemorrhage	SEVERE
23	--/--/2013 --/--/2013	Procedure Hysterectomy	(UNKNOWN ASSOCIATED CONDITION)
24	--/--/2018 Ongoing	Current Condition Gastroesophageal reflux disease	
25	--/--/2019 --/--/2019	Procedure Laparotomy	LYSIS OF ADHESIONS (UNKNOWN ASSOCIATED CONDITION)
26	--/--/2019 Ongoing	Current Condition Arrhythmia	(UNKNOWN TYPE)
27	--/--/2020 Ongoing	Current Condition Insomnia	
28	--/--/2020 Ongoing	Current Condition Attention deficit hyperactivity disorder	
29	08/24/2020 Ongoing	Current Condition Tinnitus	

C4. DIAGNOSIS FOR USE (Continued)

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

C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

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

- 2) METOPROLOL (METOPROLOL) 01/--/2020 to ongoing
- 3) SERTRALINE (SERTRALINE) --/--/2002 to ongoing
- 4) OLMESARTAN/HCTZ KRKA (HYDROCHLOROTHIAZIDE, OLMESARTAN MEDOXOMIL) --/--/2006 to ongoing
- 5) HYDROCODONE (HYDROCODONE) --/--/2006 to ongoing
- 6) METAXALONE (METAXALONE) --/--/2016 to ongoing
- 7) GABAPENTIN (GABAPENTIN) --/--/2006 to ongoing
- 8) ADDERALL (AMFETAMINE ASPARTATE, AMFETAMINE SULFATE, DEXAMFETAMINE SACCHARATE, DEXAMFETAMINE SULFATE) --/--/2020 to ongoing

## 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.	09/21/2020 to 09/21/2020	Blinded	Blinded



**MEDWATCH**

3500A Facsimile

For use by user-facilities,  
importers, distributors and manufacturers  
for MANDATORY reporting

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

Page 1 of 5

A. PATIENT INFORMATION			
1. Patient Identifier US3452332	2. Age at Time of Event: 65 Years or Date of Birth: (b) (6)/1955	3. Sex <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight 222.0 lbs or 100.7 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"/> 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) 10/26/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) COVID 19 [COVID-19]  Case Description: This 65-year-old, White, male subject (US3452332) 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 the non-serious event of COVID 19.  The subject's medical history, as provided by the investigator, included anxiety, seasonal allergies, disc repair of back, allergy to penicillin, back pain, gastroesophageal reflux disease, high cholesterol, diabetes type II, edema in both feet, headaches, vasectomy, heart attack and hypertension. continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 10/26/2020 Blood pressure measurement (continued) #2 10/26/2020 Body temperature 98.7 °F #3 10/27/2020 Body temperature 98.7 °F #4 10/28/2020 Body temperature 99.3 °F #5 10/29/2020 Body temperature 99.5 °F #6 10/30/2020 Body temperature 101.2 °F continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/1985 to Ongoing Current Condition, (Continued) #2 --/--/1995 to Ongoing Allergy, (Continued) #3 --/--/1995 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. 08/07/2020 to 08/07/2020	
#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) ALPRAZOLAM (ALPRAZOLAM) --/--/2005 to ongoing 2) AMLODIPINE (AMLODIPINE) --/--/2005 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 Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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 type="checkbox"/> Follow-up #			
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) COVID-19		
E. INITIAL REPORTER			
1. Name and Address Dr. Carl Griffin Lynn Health Science Institute Oklahoma City, Oklahoma UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @lhsi.net	
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)

Concomitant medications reported included alprazolam, amlodipine, metformin, rosuvastatin, ibuprofen, furosemide and digoxin.

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 07 Aug 2020. The subject's last dose of study drug prior to event onset was on 03 Sep 2020.

The subject had an occupational risk (truck driver) of exposure for COVID-19.

On 26 Oct 2020, the subject experienced COVID 19 with a positive SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab. No treatment information was reported by the investigator.

From 26 Oct 2020 through 13 Nov 2020, the subject intermittently experienced mild to moderate chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, loss of taste, loss of smell, nasal congestion, runny nose (rhinorrhea), nausea, diarrhea, and sore throat. He denied experiencing vomiting.

From 30 Oct 2020 through 01 Nov 2020, temperature was 101.2-100.4 degrees Fahrenheit (F).

On 31 Oct 2020, oxygen saturation was 91%.

On 02 Nov 2020, temperature normalized, 99.3 F.

On 03 Nov 2020, oxygen saturation was 93%.

On 04 Nov 2020, oxygen saturation normalized, 97%.

The action taken with the study drug dosing was not applicable as the subject had already received both scheduled doses.

The event, COVID 19, was reported as not resolved.

The investigator assessed the event, COVID 19, as not related to study drug and not related to study procedure.

Follow-up received on 10 Nov 2020 included updated event details, action taken.

Follow-up received on 19 Nov 2020 updated symptom dates and laboratory results.

### Case Comment/Sender's Comment:

Company Comment: This case concerns a 65-year-old, White, male subject who experienced an unexpected event of COVID 19. The event occurred 2 months 20 days after the first dose of blinded study vaccine administration and 1 month 24 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	10/26/2020	Blood pressure measurement	122/74 mmHg	
7	10/31/2020	Body temperature	101.2 °F	
8	11/01/2020	Body temperature	100.4 °F	
9	11/02/2020	Body temperature	99.3 °F	
10	11/03/2020	Body temperature	97.3 °F	
11	11/04/2020	Body temperature	98.3 °F	
12	11/05/2020	Body temperature	97.6 °F	
13	11/06/2020	Body temperature	96.2 °F	

FDA-CBER-2022-1614-4433534

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

14	11/07/2020	Body temperature	98.4 °F
15	11/08/2020	Body temperature	97.9 °F
16	11/09/2020	Body temperature	97.8 °F
17	11/10/2020	Body temperature	97.0 °F
18	11/11/2020	Body temperature	97.9 °F
19	11/12/2020	Body temperature	97.9 °F
20	11/13/2020	Body temperature	98.3 °F
21	11/14/2020	Body temperature	98.7 °F
22	11/15/2020	Body temperature	98.3 °F
23	11/16/2020	Body temperature	97.9 °F
24	11/17/2020	Body temperature	97.7 °F
25	11/18/2020	Body temperature	97.6 °F
26	11/19/2020	Body temperature	97.9 °F
27	11/20/2020	Body temperature	98.1 °F
28	10/26/2020	Heart rate	74 heart beats per minute
29	10/26/2020	Oxygen saturation	98 percent
30	10/27/2020	Oxygen saturation	97 percent
31	10/28/2020	Oxygen saturation	94 percent
32	10/29/2020	Oxygen saturation	94 percent
33	10/30/2020	Oxygen saturation	97 percent
34	10/31/2020	Oxygen saturation	91 percent
35	11/01/2020	Oxygen saturation	96 percent
36	11/02/2020	Oxygen saturation	97 percent
37	11/03/2020	Oxygen saturation	93 percent
38	11/04/2020	Oxygen saturation	97 percent
39	11/05/2020	Oxygen saturation	97 percent
40	11/06/2020	Oxygen saturation	95 percent

FDA-CBER-2022-1614-4433535

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

41	11/07/2020	Oxygen saturation	97 percent
42	11/08/2020	Oxygen saturation	97 percent
43	11/09/2020	Oxygen saturation	97 percent
44	11/10/2020	Oxygen saturation	96 percent
45	11/11/2020	Oxygen saturation	99 percent
46	11/12/2020	Oxygen saturation	97 percent
47	11/13/2020	Oxygen saturation	97 percent
48	11/14/2020	Oxygen saturation	98 percent
49	11/15/2020	Oxygen saturation	98 percent
50	11/16/2020	Oxygen saturation	97 percent
51	11/17/2020	Oxygen saturation	98 percent
52	11/18/2020	Oxygen saturation	98 percent
53	11/19/2020	Oxygen saturation	98 percent
54	11/20/2020	Oxygen saturation	97 percent
55	10/26/2020	Respiratory rate	12 breaths per minute
56	10/26/2020	SARS-CoV-2 test Positive Nasopharyngeal swab	

## B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1985 Ongoing	Current Condition Headache	
2	--/--/1995 Ongoing	Allergy Drug hypersensitivity	
3	--/--/1995 Ongoing	Current Condition Oedema peripheral	Both
4	--/--/1995 --/--/1995	Historical Condition Myocardial infarction	
5	--/--/1995 Ongoing	Current Condition Hypertension	

6	--/--/1997 --/--/1997	Procedure Vasectomy
7	--/--/2001 Ongoing	Allergy Seasonal allergy
8	--/--/2005 Ongoing	Current Condition Anxiety
9	--/--/2010 Ongoing	Current Condition Blood cholesterol increased
10	--/--/2015 Ongoing	Current Condition Back pain
11	--/--/2016 --/--/2016	Procedure Intervertebral disc operation
12	--/--/2018 Ongoing	Current Condition Gastroesophageal reflux disease
13	06/--/2019 Ongoing	Current Condition Type 2 diabetes mellitus

#### C4. DIAGNOSIS FOR USE (Continued)

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

#### C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

- 3) METFORMIN (METFORMIN) 06/--/2019 to ongoing
- 4) ROSUVASTATIN (ROSUVASTATIN) --/--/2010 to ongoing
- 5) IBUPROFEN (IBUPROFEN) --/--/2015 to ongoing
- 6) FUROSEMIDE (FUROSEMIDE) --/--/1995 to ongoing
- 7) DIGOXIN (DIGOXIN) --/--/1995 to ongoing

#### 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.	09/03/2020 to 09/03/2020	Blinded	Blinded

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

A. PATIENT INFORMATION			
1. Patient Identifier US3902015	2. Age at Time of Event: 53 Years or Date of Birth: (b) (6) 1966	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 268.0 lbs or 121.5 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"/> 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) 10/26/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) COVID-19 [COVID-19]  Case Description: This 53-year-old, black, female subject (US3902015), 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 the non-serious event of COVID-19.  The subject's medical history, as provided by the investigator, included generalized back pain, bilateral lower leg swelling, back muscle spasms, morbid obesity and postmenopausal. Concomitant medications reported included meloxicam, hydrochlorothiazide, cyclobenzaprine and baclofen. continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates			
#1 10/28/2020 Blood pressure measurement (continued) #2 10/28/2020 Body temperature 100.0 °F #3 10/29/2020 Body temperature 102.4 °F #4 10/30/2020 Body temperature 100.1 °F #5 10/31/2020 Body temperature 99.7 °F #6 11/01/2020 Body temperature 98.3 °F continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: Black #1 --/--/1996 to Ongoing Current Condition, (Continued) #2 --/--/2009 to Ongoing Current Condition, (Continued) #3 --/--/2016 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. 09/08/2020 to 09/08/2020	
#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) MELOXICAM (MELOXICAM) --/--/2018 to ongoing			
2) HYDROCHLOROTHIAZIDE (HYDROCHLOROTHIAZIDE) continued in additional info section...			
G. ALL MANUFACTURERS			
1. Contact Office (and Manufacturing Site for Devices)		2. Phone Number	
Name ModernaTX, Inc. David Martin Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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) 11/23/2020	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 type="checkbox"/> Follow-up #			
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) COVID-19		
E. INITIAL REPORTER			
1. Name and Address Dr. MURRAY KIMMEL Synexus - Optimal Research - Melbourne Melbourne, Florida UNITED STATES			
Phone # (b) (6)	Email Address (b) (6) @optimalsites.net		
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)

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 08 Sep 2020. The subject's last dose of study drug prior to event onset was on 06 Oct 2020.

On 26 Oct 2020, the subject experienced COVID-19. From 26 Oct 2020 to 09 NOV 2020 the subject intermittently experienced mild to moderate symptoms of chills, cough, fatigue, body aches, nasal congestion, muscle aches, headache, runny nose, sore throat, shortness of breath, difficulty breathing, nausea and diarrhea. Subject denied new loss of taste, new loss of smell and vomiting.

On 27 Oct 2020, treatment included naproxen sodium.

On 28 Oct 2020, a SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab was positive. Vital signs include pulse rate 95 beats/min, respiratory rate 16 breaths/min, blood pressure 122/70 mmHg and temperature 100.0 degrees Fahrenheit. Differential diagnosis was viral syndrome, caused by COVID-19. The subject was undergoing further evaluation by the primary care physician. The subject was an educator or student in the school setting, who resided in a single-family home (COVID-19 risk of exposure factors).

On 29 Oct 2020, temperature was 102.4 degrees Fahrenheit.

On 02 Nov 2020, treatment included acetaminophen/diphenhydramine hcl/phenylephrine hcl.

On 04 Nov 2020, temperature was 98.5 degrees Fahrenheit and remained normal.

On 06 Nov 2020, oxygen saturation was 92%.

On 07 Nov 2020, oxygen saturation was 97% and remained normal.

The action taken with study drug in response to the event was reported as not applicable.

The event, COVID-19, was reported as resolving.

The investigator assessed the event, COVID-19, as not related to study drug or study procedure.

Follow-up received on 23 Nov 2020, included updated event term COVID-19 (previously symptomatic COVID-19), vital signs, symptom log, medical history, concomitant medication, treatment and outcome.

### Case Comment/Sender's Comment:

Company Comment: This case concerns a 53-year-old, black, female subject with medical history of morbid obesity, who experienced an unexpected event of symptomatic COVID-19. The event occurred 1 month 19 days after the first dose of blinded study vaccine administration and 21 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	10/28/2020	Blood pressure measurement	122/70 mmHg	
7	11/02/2020	Body temperature	98.4 °F	
8	11/03/2020	Body temperature	101.0 °F	
9	11/04/2020	Body temperature	98.5 °F	
10	11/06/2020	Body temperature	99.1 °F	
11	11/07/2020	Body temperature	97.9 °F	

FDA-CBER-2022-1614-4433539



12	11/08/2020	Body temperature	98.1 °F
13	11/10/2020	Body temperature	97.1 °F
14	10/28/2020	Heart rate	95 /min
15	10/29/2020	Oxygen saturation	98 percent
16	10/30/2020	Oxygen saturation	98 percent
17	10/31/2020	Oxygen saturation	98 percent
18	11/01/2020	Oxygen saturation	98 percent
19	11/02/2020	Oxygen saturation	97 percent
20	11/03/2020	Oxygen saturation	96 percent
21	11/04/2020	Oxygen saturation	95 percent
22	11/06/2020	Oxygen saturation	92 percent
23	11/07/2020	Oxygen saturation	97 percent
24	11/08/2020	Oxygen saturation	98 percent
25	11/10/2020	Oxygen saturation	98 percent
26	10/28/2020	Respiratory rate	16 breaths
27	10/28/2020	SARS-CoV-2 test Positive Nasopharyngeal swab	

## B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1996 Ongoing	Current Condition Obesity	
2	--/--/2009 Ongoing	Current Condition Back pain	Generalized
3	--/--/2016 Ongoing	Current Condition Muscle spasms	BACK
4	--/--/2018 Ongoing	Current Condition Oedema peripheral	Bilateral lower swelling
5	08/--/2019 Ongoing	Current Condition Menopausal symptoms	

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

## C4. DIAGNOSIS FOR USE (Continued)

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

## C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

--/--/2019 to ongoing

3) CYCLOBENZAPRINE (CYCLOBENZAPRINE) --/--/2016 to 10/02/2020

4) BACLOFEN (BACLOFEN) 10/03/2020 to ongoing

## 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.	10/06/2020 to 10/06/2020	Blinded	Blinded

**MEDWATCH**

3500A Facsimile

For use by user-facilities,  
importers, distributors and manufacturers  
for MANDATORY reporting

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

Page 1 of 4

A. PATIENT INFORMATION			
1. Patient Identifier US3842040	2. Age at Time of Event: 49 Years or Date of Birth: (b) (6)/1971	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 type="checkbox"/> Death: _____ (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) 11/03/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) COVID-19 [COVID-19]			
Case Description: This 49-year-old, Hispanic or Latino, female subject (US3842040) 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 the non-serious event of COVID-19.			
The subject's medical history, as provided by the investigator, included hypertension, hypercholesterol, latex allergy, mango allergy, type 2 diabetes, moderate asthma, acid reflux, seasonal allergies, occasional tension headache, and osteoarthritis, right knee. Concomitant medications included continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates			
#1 11/03/2020 Blood pressure measurement (continued)			
#2 11/03/2020 Body temperature (continued)			
#3 11/03/2020 Heart rate 80 /min			
#4 11/03/2020 Oxygen saturation 97 percent			
#5 11/08/2020 Oxygen saturation 92 percent			
#6 11/09/2020 Oxygen saturation 97 percent			
continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/1979 to Ongoing Current Condition, (Continued) #2 --/--/1986 to Ongoing Current Condition, (Continued) #3 --/--/1995 to Ongoing Allergy, (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. 09/18/2020 to 09/18/2020	
#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) ALLEGRA (FEXOFENADINE HYDROCHLORIDE) --/--/2010 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 Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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) 11/23/2020	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 type="checkbox"/> Follow-up # _____		
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) COVID-19		
E. INITIAL REPORTER			
1. Name and Address Dr. Shobha Swaminathan New Jersey Medical School 185, South Orange Ave Newark, New Jersey 07103 UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @njms.rutgers.edu	
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)

feofenadine hydrochloride, budesonide/ formoterol fumarate, esomeprazole sodium, fluticasone propionate, hyaluronate sodium, paracetamol, salbutamol, amlodipine besilate, losartan, atorvastatin, montelukast sodium, metformin, fluticasone propionate/ salmeterol xinafoate, and dextromethorphan hydrobromide/doxylamine succinate/ephedrine sulfate/ethanol/paracetamol.

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 18 Sep 2020. The subject's last dose of study drug prior to event onset was on 16 Oct 2020.

The subject had an occupational risk (healthcare worker) and location and living circumstances risk (resided in a single-family home) of exposure for COVID-19.

On 03 Nov 2020, the subject experienced the event of COVID-19 with positive SARS-CoV-2 real time reverse transcriptase polymerase chain reaction testing via nasal pharyngeal swab. Vital signs included temperature 98.5 degrees Fahrenheit, oxygen saturation 97%, pulse 80 beats/min, respiratory rate 16 breaths/min and blood pressure 122/68 mmHg. That day, the subject was treated with oral ibuprofen for headache.

From 03 Nov 2020 through 25 Nov 2020, the subject intermittently experienced mild sore throat, moderate headache, as well as mild to moderate cough, fatigue, muscle and body aches, chills, shortness of breath, difficulty breathing, new losses of taste and smell, nasal congestion, nausea, and runny nose.

On 07 Nov 2020, the subject received respiratory budesonide/formoterol for shortness of breath.

On 08 Nov 2020, the subject's oxygen saturation was 92%.

On 09 Nov 2020, the subject was treated with oral ondansetron for nausea.

On 10 Nov 2020, the subject was treated with oral methylprednisolone for COVID-19, respiratory salbutamol for shortness of breath and oral benzonatate for cough. Additionally, the subject's oxygen saturation was 93%.

On 11 Nov 2020, the subject was treated with oral paracetamol for headache.

On 14 Nov 2020, the subject was treated with oral ibuprofen for headache.

Action taken with the study drug in response to the event of COVID-19 was reported as not applicable.

The event, COVID-19, was considered not recovered.

The investigator assessed the event, COVID-19, as not related to study drug and not related to study procedure.

Follow-up information received on 23 Nov 2020 and 01 Dec 2020 included updated event term of COVID-19 (prev. positive COVID-19 dx), and updated action taken (prev. no change), treatment details, medical history, symptoms and vital signs.

#### Case Comment/Sender's Comment:

Company Comment: This case concerns a 49-year-old, Hispanic or Latino, female subject with medical history of hypertension, hypercholesterol, type 2 diabetes, and moderate asthma, who experienced an unexpected event of positive COVID-19 dx. The event occurred 1 month 17 days after the first dose of blinded study vaccine administration and 19 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	11/03/2020	Blood pressure measurement	122/68 mmHg	
2	11/03/2020	Body temperature	98.5 °F	
		Oral		
7	11/10/2020	Oxygen saturation	93 percent	FDA-CBER-2022-1614-4433543

8	11/11/2020	Oxygen saturation	96 percent
9	11/03/2020	Respiratory rate	16 /min
10	11/03/2020	SARS-CoV-2 test Positive Nasopharyngeal swab	

## B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1979 Ongoing	Current Condition Tension headache	Occasional
2	--/--/1986 Ongoing	Current Condition Asthma	Moderate
3	--/--/1995 Ongoing	Allergy Rubber sensitivity	
4	--/--/1998 Ongoing	Allergy Food allergy	
5	--/--/2005 Ongoing	Current Condition Seasonal allergy	
6	--/--/2010 Ongoing	Current Condition Osteoarthritis	Right
7	--/--/2012 Ongoing	Current Condition Hypertension	
8	--/--/2013 Ongoing	Current Condition Type 2 diabetes mellitus	
9	--/--/2014 Ongoing	Current Condition Hypercholesterolaemia	
10	--/--/2019 Ongoing	Current Condition Gastroesophageal reflux disease	

## C4. DIAGNOSIS FOR USE (Continued)

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

## C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

- 2) SYMBICORT (BUDESONIDE, FORMOTEROL FUMARATE) 01/01/2020 to ongoing
- 3) ESOMEPRazole SODIUM (ESOMEPRazole SODIUM) --/--/2019 to ongoing
- 4) FLONASE [FLUTICASONE PROPIONATE] (FLUTICASONE PROPIONATE) --/--/2005 to ongoing
- 5) EUFLEXXA (HYALURONATE SODIUM) , 1 percent --/--/2011 to ongoing
- 6) TYLENOL (PARACETAMOL) 10/19/2020 to ongoing

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

- 7) TYLENOL (PARACETAMOL) 10/19/2020 to ongoing
- 8) TYLENOL ARTHRITIS (PARACETAMOL) 11/02/2020 to ongoing
- 9) NYQUIL (DEXTROMETHORPHAN HYDROBROMIDE, DOXYLAMINE SUCCINATE, EPHEDRINE SULFATE, ETHANOL, PARACETAMOL) 11/01/2020 to ongoing
- 10) ALBUTEROL [SALBUTAMOL] (ALBUTEROL [SALBUTAMOL]) --/--/1986 to ongoing
- 11) NORVASC (AMLODIPINE BESILATE) 03/01/2012 to ongoing
- 12) LOSARTAN (LOSARTAN) 04/--/2016 to ongoing
- 13) ATORVASTATIN (ATORVASTATIN) --/--/2014 to ongoing
- 14) SINGULAIR (MONTELUKAST SODIUM) --/--/2019 to ongoing
- 15) METFORMIN (METFORMIN) --/--/2013 to ongoing
- 16) WIXELA INHUB (FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE) --/--/2019 to ongoing

## 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.	10/16/2020 to 10/16/2020	Blinded	Blinded

**MEDWATCH**

3500A Facsimile

For use by user-facilities,  
importers, distributors and manufacturers  
for MANDATORY reporting

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

Page 1 of 4

A. PATIENT INFORMATION			
1. Patient Identifier US3312605	2. Age at Time of Event: 24 Years or Date of Birth: (b) (6)/1996	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"/> 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) 10/19/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) SYMPTOMATIC COVID 19 [COVID-19]			
Case Description: This 24-year-old, White, male subject (US3312605) 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 the non serious adverse event of symptomatic COVID-19.			
The subject's medical history, as provided by the investigator, included nose fracture, depression, reconstructive nasal surgery, anxiety, attention deficit hyperactivity disorder, excessive hair loss, seasonal allergies, continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 10/21/2020 Body temperature (continued) #2 10/27/2020 Oxygen saturation 85 percent #3 11/04/2020 Oxygen saturation 98 percent #4 11/04/2020 Physical examination normal #5 10/20/2020 SARS-CoV-2 test Positive #6 10/27/2020 SARS-CoV-2 test (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 --/--/2001 Historical Condition, (Continued) #2 --/--/2001 to --/--/2001 Procedure, (Continued) #3 --/--/2010 to --/--/2010 Historical Condition, (Continued) continued in additional info section...			

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event

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. 09/10/2020 to 09/10/2020	
#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) ESCITALOPRAM (ESCITALOPRAM) --/--/2016 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 Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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) 11/12/2020		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 type="checkbox"/> Follow-up # _____			
9. Manufacturer Report Number (b) (6)		8. Adverse Event Term(s) COVID-19	
E. INITIAL REPORTER			
1. Name and Address Dr CARLOS FIERRO Johnson County Clin-Trials 16300 COLLEGE BLVD SHAWNEE, KS 66219 UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @jcct.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	

## ADDITIONAL INFORMATION

### B5. EVENT DESCRIPTION (Continued)

mild occasional headaches, recurrent tonsillitis, tonsillectomy and recurrent nephrolithiasis. Concomitant medications reported included escitalopram, amphetamine aspartate monohydrate/ amphetamine sulfate/ dexamfetamine saccharate/ dexamfetamine sulfate, finasteride, potassium citrate, cetirizine and paracetamol.

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 10 Sep 2020. The subject's last dose of study drug prior to event onset was on 08 Oct 2020.

From 19 Oct 2020 through 4 Nov 2020 subject intermittently experienced moderate cough, severe fatigue, severe body and muscle aches, severe nausea, severe vomiting, severe diarrhea, severe sore throat, moderate chills, severe shortness of breath, severe difficulty breathing, severe nasal congestion, as well as severe loss of taste and smell. Subject denied any rhinorrhea. Treatment included oral acetaminophen/dextromethorphan/phenylephrine, oral acetaminophen/doxylamine/dextromethorphan, oral acetaminophen, and oral ibuprofen. On 20 Oct 2020, the subject had a SARS-CoV-2 real-time reverse transcription polymerase chain reaction (RT-PCR) nasopharyngeal swab, which resulted positive on 22 Oct 2020. Treatment included oral zinc, oral melatonin, oral famotidine and oral ascorbic acid. On 25 Oct 2020, treatment included albuterol inhaler.

On 27 Oct 2020, due to worsening of symptoms, subject was admitted to the hospital. A SARS-CoV-2 by RT-PCR nasopharyngeal swab performed and was reported as positive. His oxygen saturation was 85%. Treatment included benzonatate, albuterol sulfate nebulizer, and intravenous hydration. Post treatment, oxygen saturation was considered much improved without the use of supplemental oxygen. The site reports that the subject had no known exposure or risk factors for COVID-19.

On 29 Oct 2020, the subject was discharged from the hospital. On 02 Nov 2020, he reported steady improvement since discharge, with resolution of symptoms. On 04 Nov 2020, at site visit, the subject's physical examination was normal. Oxygen saturation was 98%. It was noted that the subject did not report symptoms during his illness as he "felt too bad to do anything".

Subject notified the site that he wished to no longer participate in the study and gave no reason. Investigator reported that they are unable to confirm the subjects account of COVID-19 illness, as the hospital at which he reported being admitted has no record of admission. Also, the subject did not produce a copy of his initial SARS-CoV-2 test. Investigator noted that subject reported that he never received supplemental oxygen even though his oxygen saturation was reported to be as low as 85%. Investigator noted that he doubted the veracity of his story since this was inconsistent with standards of care. Investigator mentioned that the subject had a history of noncompliance with his diaries and clarification was needed on final resolution since what subject reported to the site staff was inconsistent. Investigator doubted the accuracy of the subject's reporting.

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

The event, symptomatic COVID-19, was considered resolved on 02 Nov 2020.

The investigator assessed the event, symptomatic COVID-19, as not related to study drug or study procedure.

Follow-up received on 16 Nov 2020 included confirmation of severity, and event details.

### Case Comment/Sender's Comment:

This case concerns a 24- year-old male subject who experienced an unexpected event of COVID-19. The event occurred 12 days after the second dose of blinded study medication administration. The event was considered unrelated to the blinded study medication in agreement with the Investigator.

### B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	10/21/2020	Body temperature	101.9 OTHER	
6	10/27/2020	SARS-CoV-2 test Positive Nasopharyngeal swab		



## B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/2000 --/--/2001	Historical Condition Tonsillitis	
2	--/--/2001 --/--/2001	Procedure Tonsillectomy	
3	--/--/2010 --/--/2010	Historical Condition Facial bones fracture	Fracture
4	--/--/2010 --/--/2010	Procedure Nasal operation	Reconstruction
5	--/--/2010 Ongoing	Current Condition Seasonal allergy	
6	--/--/2010 Ongoing	Current Condition Headache	Mild occasional
7	--/--/2011 Ongoing	Current Condition Attention deficit hyperactivity disorder	
8	--/--/2016 Ongoing	Current Condition Depression	
9	--/--/2016 Ongoing	Current Condition Anxiety	
10	--/--/2016 Ongoing	Current Condition Nephrolithiasis	
11	--/--/2019 Ongoing	Current Condition Alopecia	Excessive

## C4. DIAGNOSIS FOR USE (Continued)

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

## C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

2) DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE MONOHYDRATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE (AMFETAMINE ASPARTATE MONOHYDRATE, AMFETAMINE SULFATE, DEXAMFETAMINE SACCHARATE, DEXAMFETAMINE SULFATE) --/--/2011 to ongoing

3) FINASTERIDE (FINASTERIDE) --/--/2019 to ongoing

4) POTASSIUM CITRATE (POTASSIUM CITRATE) --/--/2016 to ongoing

5) CETIRIZINE (CETIRIZINE) --/--/2010 to ongoing

## Block C - Additional Dosage Regimens

Suspect Product                      2. Dose, frequency & route used    3. Therapy dates                      6. Lot #                      7. Exp. date

FDA-CBER-2022-1614-4433548

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

(if unknown, give duration)

#1 mRNA-1273 vs Placebo Regimen # 2	Blinded, Information withheld.	10/08/2020 to 10/08/2020	Blinded	Blinded
--	--------------------------------	--------------------------	---------	---------

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

A. PATIENT INFORMATION			
1. Patient Identifier US3272195	2. Age at Time of Event: 44 Years or Date of Birth: (b) (6)/1976	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 164.9 lbs or 74.8 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"/> Disability or Permanent Damage <input type="checkbox"/> Life-threatening <input type="checkbox"/> Congenital Anomaly/Birth Defect <input checked="" 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) 10/30/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) PNEUMONIA DUE TO COVID-19 VIRUS [COVID-19 pneumonia] COVID 19 [COVID-19] HYPOXIA [Hypoxia]  Case Description: Cohort: >=18 and <65 years and not at risk Date of Birth: 1976 (b) (6)  AE: COVID-19 Start Date: 20201030 SAE Description: PARTICIPANT WAS EXPOSED TO COWORKER WITH COVID-19 AND TESTED POSITIVE 01NOV2020 AS DID HER FAMILY MEMBERS. OXYGEN SATURATIONS ARE IN THE UPPER 80S AND continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 11/02/2020 Blood pressure measurement (continued) #2 10/31/2020 Body temperature 99.0 °F #3 11/02/2020 Body temperature (continued) #4 11/03/2020 Body temperature 101.2 °F #5 11/04/2020 Body temperature 100.4 °F #6 11/05/2020 Body temperature 100.4 °F continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/1992 to Ongoing Current Condition, (Continued) #2 --/--/1992 to UNK Current Condition, (Continued) #3 --/--/2007 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. 08/19/2020 to 08/19/2020	
#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) ALLEGRA-D [FEXOFENADINE HYDROCHLORIDE;PSEUDOEPHEDRINE HYDROCHLORIDE] continued in additional info section...			
G. ALL MANUFACTURERS			
1. Contact Office (and Manufacturing Site for Devices)		2. Phone Number	
Name ModernaTX, Inc. David Martin Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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 # 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 type="checkbox"/> Follow-up #			
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) COVID-19 pneumonia, COVID-19, Hypoxia		
E. INITIAL REPORTER			
1. Name and Address Dr. ADAM BROSZ Meridian Clinical Research 2444 W. FAIDLEY AVE GRAND ISLAND, NE 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)

PRESENTED TO THE ED. DIAGNOSED WITH ACUTE HYPOXIC RESPIRATORY FAILURE REQUIRING SUPPLEMENTAL OXYGEN UP TO 3L/NC. HER CHEST X-RAY ON 7NOV2020 SHOWED MULTIFOCAL PNEUMONIA. SHE WAS GIVEN DEXAMETHASONE, AZITHROMYCIN 500 MG IV Q24HOUR, BRONCHODILATOR TREATMENT, ACETAMINOPHEN, IBUPROFEN, AND REMDESEVIR. HYPOKALEMIA WAS FOUND INCIDENTALLY DURING HER HOSPITALIZATION AND SHE WAS STARTED ON POTASSIUM CHLORIDE AS WELL.

PARTICIPANT REMAINED ON A NON-ICU FLOOR UNTIL DISCHARGE ON 12NOV2020. SENT HOME ON ROOM AIR WITH PRESCRIPTIONS FOR AZITHROMYCIN 250 MG TABLET- 500 MG ON DAY ONE AND THEN 250 MG TABLET ON DAYS 2-5, DEXAMETHASONE 6 MG ONCE DAILY X 4 DAYS, AND POTASSIUM CHLORIDE 10 MEQ BID X 7 DAYS. SHE WAS SET TO FOLLOW UP WITH HER PRIMARY CARE PHYSICIAN IN 3-5 DAYS.

Requires inpatient or prolongation of existing Hospitalization: Yes

Action Taken: Not Applicable

Action Taken ER Visit: 1

Related to procedure: Not Related

Severity: Grade 4

Date of hospital admission: 20201107

Date of hospital discharge: 20201112

Admitted to ICU?: No

AE: PNEUMONIA DUE TO COVID-19 VIRUS

Start Date: 20201107

SAE Description: SUBJECT ADMITTED TO HOSPITAL ON 07NOV2020 DUE ACUTE RESPIRATORY FAILURE DUE TO COVID-19 AND PNEUMONIA DUE TO COVID-19 VIRUS.

PARTICIPANT WAS EXPOSED TO COWORKER WITH COVID-19 AND TESTED POSITIVE 01NOV2020 AS DID HER FAMILY MEMBERS. OXYGEN SATURATIONS ARE IN THE UPPER 80S AND PRESENTED TO THE ED. DIAGNOSED WITH ACUTE HYPOXIC RESPIRATORY FAILURE REQUIRING SUPPLEMENTAL OXYGEN UP TO 3L/NC. HER CHEST X-RAY ON 7NOV2020 SHOWED MULTIFOCAL PNEUMONIA- NO REPEAT X-RAY. SHE WAS GIVEN DEXAMETHASONE, AZITHROMYCIN 500 MG IV Q24HOUR, BRONCHODILATOR TREATMENT, ACETAMINOPHEN, IBUPROFEN, AND REMDESEVIR.

PARTICIPANT REMAINED ON A NON-ICU FLOOR UNTIL DISCHARGE ON 12NOV2020. SENT HOME ON ROOM AIR WITH PRESCRIPTIONS FOR AZITHROMYCIN 250 MG TABLET- 500 MG ON DAY ONE AND THEN 250 MG TABLET ON DAYS 2-5, DEXAMETHASONE 6 MG ONCE DAILY X 4 DAYS, AND POTASSIUM CHLORIDE 10 MEQ BID X 7 DAYS. SHE WAS SET TO FOLLOW UP WITH HER PRIMARY CARE PHYSICIAN IN 3-5 DAYS. RESPIRATORY SYMPTOMS RESOLVED 30NOV2020 WITH PNEUMONIA RESOLUTION.

Requires inpatient or prolongation of existing Hospitalization: Yes

Action Taken: Not Applicable

Action Taken ER Visit: 1

Related to procedure: Not Related

Severity: Grade 4

Date of hospital admission: 20201107

Date of hospital discharge: 20201112

Admitted to ICU?: No

AE: HYPOXIA

Start Date: 20201107

SAE Description: SUBJECT ADMITTED TO HOSPITAL ON 07NOV2020 DUE TO WORSENING SYMPTOMS OF COVID 19 POSITIVE ILLNESS WITH SECONDARY PNEUMONIA THAT BEGAN BEING TREATED IN PATIENT 07NOV2020. SHE WAS ALSO GIVEN SUPPLEMENTAL OXYGEN DUE TO HYPOXIA.

PARTICIPANT WAS EXPOSED TO COWORKER WITH COVID-19 AND TESTED POSITIVE 01NOV2020 AS DID HER FAMILY

FDA-CBER-2022-1614-4433551

MEMBERS. OXYGEN SATURATIONS ARE IN THE UPPER 80S AND PRESENTED TO THE ED. DIAGNOSED WITH ACUTE HYPOXIC RESPIRATORY FAILURE REQUIRING SUPPLEMENTAL OXYGEN UP TO 3L/NC. HER CHEST X-RAY ON 7NOV2020 SHOWED MULTIFOCAL PNEUMONIA. SHE WAS GIVEN DEXAMETHASONE, AZITHROMYCIN 500 MG IV Q24HOUR, BRONCHODILATOR TREATMENT, ACETAMINOPHEN, IBUPROFEN, AND REMDESEVIR. HYPOKALEMIA WAS FOUND INCIDENTALLY DURING HER HOSPITALIZATION AND SHE WAS STARTED ON POTASSIUM CHLORIDE AS WELL.

PARTICIPANT REMAINED ON A NON-ICU FLOOR UNTIL DISCHARGE ON 12NOV2020. SENT HOME ON ROOM AIR WITH PRESCRIPTIONS FOR AZITHROMYCIN 250 MG TABLET- 500 MG ON DAY ONE AND THEN 250 MG TABLET ON DAYS 2-5, DEXAMETHASONE 6 MG ONCE DAILY X 4 DAYS, AND POTASSIUM CHLORIDE 10 MEQ BID X 7 DAYS. SHE WAS SET TO FOLLOW UP WITH HER PRIMARY CARE PHYSICIAN IN 3-5 DAYS.

SHE IS RECOVERED. PRESENTED FOR DAY 28 CONVALESCENT VISIT ON 30NOV2020. LUNGS CLEAR TO AUSCULTATION, BREATHING WITHOUT EFFORT, NO SUPPLEMENTAL O2, NO RESPIRATORY, PNEUMONIA, OR COVID MEDICATIONS, NO RESPIRATORY SYMPTOMS.

Requires inpatient or prolongation of existing Hospitalization: Yes

Action Taken: Not Applicable

Action Taken ER Visit: 1

Related to procedure: Not Related

Severity: Grade 3/Severe

Date of hospital admission: 20201107

Date of hospital discharge: 20201112

Admitted to ICU?: No

Number of ICU days: 0

Study Drug iterations first and closest:

Study Drug First Start Date: 20200819

Study Drug First Start Time:

Study Drug Latest Start Date: 20200917

Study Drug Latest Start Time:

This 44-year-old, Hispanic or Latino, White, female subject (US3272195) 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 COVID 19, pneumonia secondary to COVID 19 positive infection, and hypoxia.

The subject's medical history, as provided by the investigator, included seasonal allergies, generalized lumbar backache, gestational diabetes, sciatica, and acid indigestion. Concomitant medications reported included fexofenadine hydrochloride/ pseudoephedrine hydrochloride, ibuprofen, calcium carbonate, fluticasone propionate, influenza vaccine, vitamin D (nos), fluconazole, and enoxaparin sodium.

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 19 Aug 2020. The subject's last dose of study drug prior to event onset was on 17 Sep 2020.

The subject had COVID-19 exposure from a coworker.

On 30 Oct 2020, the subject experienced COVID-19 with a positive SARS-CoV-2 real time reverse transcription polymerase chain reaction nasopharyngeal swab on 02 Nov 2020. She was treated with oral (PO) guaifenesin and PO sambucus nigra/ zinc, oral colesticaliferol and oral ascorbic acid.

From 30 Oct 2020 through 22 Nov 2020, the subject intermittently experienced mild to severe chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches, body aches, headache, loss of taste, loss of smell, nasal congestion, runny nose, nausea, and diarrhea. She denied vomiting or sore throat. From 23 Nov through 28 Nov 2020, the subject intermittently experienced mild cough, shortness of breath, and nasal congestion.

On 02 Nov 2020, treatment included PO paracetamol and PO melatonin.

From 03 Nov 2020 through 06 Nov 2020, temperature was 100.4 F to 101.2 degrees Fahrenheit (F).

From 05 Nov 2020 through 09 Nov 2020, the subject's oxygen saturation intermittently ranged from 85%-92%.

FDA-CBER-2022-1614-4433552

On 07 Nov 2020 she was hospitalized in the intensive care unit due to worsening COVID-19, pneumonia secondary to COVID-19 positive infection and hypoxia. Radiographical evidence confirmed COVID-19. Temperature returned to normal, 98.7 F. She received supplemental oxygen, intravenous (IV) antibiotics including azithromycin and ceftriaxone, PO dexamethasone, IV remdesivir, and IV convalescent plasma.

On 16 Nov 2020, the subject's oxygen saturation returned to normal, 98%.

On 12 Nov 2020, the subject was discharged from the hospital. Treatment included PO azithromycin and IV potassium.

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

The event, COVID 19, was reported as resolving. The event, pneumonia secondary to COVID 19 positive infection, was reported as not resolved. The event, hypoxia, was reported as resolved on 12 Nov 2020.

On 30 Nov 2020 pneumonia resolved. The subject presented for a convalescent visit on 30 Nov 2020. At that time lungs clear to auscultation, breathing without effort, no supplemental O2, no respiratory, pneumonia, or Covid medications, and no respiratory symptoms.

The investigator assessed the events, COVID 19, pneumonia secondary to COVID 19 positive infection, and hypoxia, as not related to study drug and not related to study procedure.

Follow-up received on 10 Nov 2020 included updated event term to COVID 19 and updated ICU assessment for event term of hypoxia.

Follow-up received on 20 Nov 2020 included updated known event details, medical history, concomitant medications, action taken with study drug, end date and outcome for event hypoxia, and severity for event pneumonia secondary to COVID-19 positive infection.

Follow-up received on 01 Dec 2020 included updated COVID-19 assessments, updated event outcome and date for pneumonia.

## Case Comment/Sender's Comment:

This case concerns a 44-year-old, female subject who experienced unexpected events of COVID 19, pneumonia secondary to COVID 19 positive infection, and hypoxia. The event of COVID 19 occurred 1 month 14 days after the second dose of blinded study medication administration. The events of pneumonia secondary to COVID 19 positive infection and hypoxia occurred 1 month 22 days after the second dose of blinded study medication administration. The events were considered unrelated to the blinded study medication in agreement with the Investigator. The subject had a known exposure to COVID-19 from a coworker.

## B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	11/02/2020	Blood pressure measurement	108/81 mmHg	
3	11/02/2020	Body temperature oral	37.6 degree Celsius	
7	11/06/2020	Body temperature	101.0 °F	
8	11/07/2020	Body temperature	98.7 °F	
9	11/08/2020	Body temperature	98.1 °F	
10	11/09/2020	Body temperature	98.6 °F	
11	11/10/2020	Body temperature	98.8 °F	
12	11/11/2020	Body temperature	98.6 °F	

FDA CBER 2022 1614 4433553

13	11/12/2020	Body temperature	98.6 °F
14	11/13/2020	Body temperature	98.6 °F
15	11/14/2020	Body temperature	98.4 °F
16	11/15/2020	Body temperature	98.4 °F
17	11/16/2020	Body temperature	98.2 °F
18	11/17/2020	Body temperature	97.9 °F
19	11/18/2020	Body temperature	98.4 °F
20	11/19/2020	Body temperature	98.6 °F
21	11/20/2020	Body temperature	98.2 °F
22	11/21/2020	Body temperature	99 °F
23	11/22/2020	Body temperature	98.6 °F
24	11/23/2020	Body temperature	97.9 °F
25	11/24/2020	Body temperature	98.7 °F
26	11/25/2020	Body temperature	97.7 °F
27	11/26/2020	Body temperature	98.1 °F
28	11/27/2020	Body temperature	98 °F
29	11/28/2020	Body temperature	98.3 °F
30	11/02/2020	Heart rate	101 heart beats per minute
31	11/02/2020	Oxygen saturation	99 percent
32	11/03/2020	Oxygen saturation	97 percent
33	11/04/2020	Oxygen saturation	94 percent
34	11/05/2020	Oxygen saturation	92 percent
35	11/06/2020	Oxygen saturation	93 percent
36	11/07/2020	Oxygen saturation	87 percent
37	11/08/2020	Oxygen saturation	95 percent
38	11/09/2020	Oxygen saturation	85 percent
39	11/10/2020	Oxygen saturation	95 percent

FDA-CBER-2022-1614-4433554

40	11/11/2020	Oxygen saturation	90 percent
41	11/12/2020	Oxygen saturation	89 percent
42	11/13/2020	Oxygen saturation	95 percent
43	11/14/2020	Oxygen saturation	93 percent
44	11/15/2020	Oxygen saturation	93 percent
45	11/16/2020	Oxygen saturation	98 percent
46	11/17/2020	Oxygen saturation	96 percent
47	11/18/2020	Oxygen saturation	96 percent
48	11/19/2020	Oxygen saturation	96 percent
49	11/20/2020	Oxygen saturation	98 percent
50	11/21/2020	Oxygen saturation	99 percent
51	11/22/2020	Oxygen saturation	98 percent
52	11/23/2020	Oxygen saturation	98 percent
53	11/24/2020	Oxygen saturation	99 percent
54	11/25/2020	Oxygen saturation	98 percent
55	11/26/2020	Oxygen saturation	98 percent
56	11/27/2020	Oxygen saturation	99 percent
57	11/28/2020	Oxygen saturation	99 percent
58	11/02/2020	Respiratory rate	18 breaths per minute
59	11/02/2020	SARS-CoV-2 test Positive Nasopharyngeal swab	
60	11/07/2020	X-ray  Radiographical evidence of COVID-19.	

## B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1992 Ongoing	Current Condition Dyspepsia	



2	--/--/1992 UNK	Current Condition Dyspepsia	
3	--/--/2007 Ongoing	Current Condition Seasonal allergy	
4	--/--/2007 --/--/2007	Historical Condition Gestational diabetes	
5	--/--/2008 --/--/2008	Historical Condition Gestational diabetes	
6	--/--/2017 Ongoing	Current Condition Sciatica	
7	--/--/2019 Ongoing	Current Condition Back pain	Generalized lumbar

## C4. DIAGNOSIS FOR USE (Continued)

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

## C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

(FEXOFENADINE HYDROCHLORIDE, PSEUDOEPHEDRINE HYDROCHLORIDE) 04/--/2016 to 10/15/2020

2) MOTRIN [IBUPROFEN] (IBUPROFEN) --/--/2019 to ongoing

3) CALCIUM CARBONATE (CALCIUM CARBONATE) --/--/1992 to ongoing

4) FLONASE [FLUTICASONE PROPIONATE] (FLUTICASONE PROPIONATE) 10/11/2020 to ongoing

5) INFLUENZA VACCINE (INFLUENZA VACCINE) 10/15/2020 to 10/15/2020

6) TYLENOL (PARACETAMOL) 11/02/2020 to UNK

7) LOVENOX HP (ENOXAPARIN SODIUM) 11/07/2020 to UNK

8) POTASSIUM (POTASSIUM) 11/12/2020 to UNK

9) FLUCONAZOLE (FLUCONAZOLE) 11/16/2020 to UNK

10) OMEPRAZOLE (OMEPRazole) 11/16/2020 to UNK

11) VITAMIN D NOS (VITAMIN D NOS) 10/30/2020 to UNK

12) VITAMIN C [ASCORBIC ACID] (VITAMIN C [ASCORBIC ACID]) 10/30/2020 to UNK

## 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.	09/17/2020 to 09/17/2020	Blinded	Blinded

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

A. PATIENT INFORMATION			
1. Patient Identifier US3382152	2. Age at Time of Event: 29 Years or Date of Birth: (b) (6)/1991	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 type="checkbox"/> Death: _____ (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) 10/28/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) COVID-19 [COVID-19]  Case Description: This 29-year-old, White, female subject (US3382152) was participating 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 the non-serious event of COVID-19.  The subject's medical history, as provided by the investigator, included asthma and anxiety. Concomitant medications reported included tramadol, ibuprofen and levonorgestrel.  continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 11/02/2020 Blood pressure measurement (continued) #2 10/29/2020 Body temperature 99.0 °F #3 10/30/2020 Body temperature 98 °F #4 11/02/2020 Body temperature 96.0 °F #5 11/07/2020 Body temperature 96 °F #6 11/08/2020 Body temperature 97.6 °F continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/1999 to --/--/2004, Historical Condition, Asthma #2 --/--/2016 to Ongoing, Current Condition, Anxiety			

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. 08/31/2020 to 08/31/2020	
#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) TRAMADOL (TRAMADOL) 10/19/2020 to 10/22/2020			
2) IBUPROFEN (IBUPROFEN) 10/19/2020 to 10/22/2020			
continued in additional info section...			
G. ALL MANUFACTURERS			
1. Contact Office (and Manufacturing Site for Devices)		2. Phone Number	
Name ModernaTX, Inc. David Martin Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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) 11/13/2020	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 type="checkbox"/> Follow-up # _____		
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) COVID-19		
E. INITIAL REPORTER			
1. Name and Address Dr. GREGG LUCKSINGER Advanced Clinical Research – Be Well MD CEDAR PARK, TX UNITED STATES			
Phone # (b) (6)	Email Address (b) (6) @velocityclinical.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)

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 31 Aug 2020. The subject's last dose of study drug prior to event onset was on 02 Oct 2020.

On 28 Oct 2020, the subject experienced COVID-19. Symptoms included mild cough, mild nasal congestion and mild runny nose. Treatment included oral cetirizine.

On 29 Oct 2020, the subject experienced the new symptoms of moderate shortness of breath and moderate difficulty breathing, mild fatigue and mild new loss of smell. Vital signs included temperature 99.0 degrees Fahrenheit (F). Treatment included oral paracetamol and ibuprofen and albuterol inhalant.

From 29 Oct through 10 Nov 2020, the subject intermittently experienced mild to moderate cough, shortness of breath, difficulty breathing, fatigue, new loss of smell, nasal congestion and runny nose. They denied experiencing chills, muscle aches, body aches, headache, new loss of taste, nausea, vomiting diarrhea or sore throat.

On 02 Nov 2020, the subject had a positive SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab. The subject's vital signs included oxygen (O2) saturation 95%, temperature 96.0 F, pulse 63 beats/min, respiratory rate 15 breaths/min and blood pressure 114/89.

On 03 Nov 2020 and 04 Nov 2020, the subject had an O2 saturation of 91%.

On 07 Nov 2020, nasal congestion resolved.

On 09 Nov 2020, cough, shortness of breath, difficulty breathing, fatigue and new loss of smell resolved.

On 10 Nov 2020, runny nose resolved.

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

The event, COVID-19, was considered resolved on 11 Nov 2020.

The investigator assessed the event, COVID-19, as not related to study drug and not related to study procedure.

Follow-up information received on 13 Nov 2020 and 17 Nov 2020 included updated end date, outcome, action taken, symptom logs and concomitant medication.

#### Case Comment/Sender's Comment:

This case concerns a 29 year old female subject with medical history of asthma, who experienced an unexpected event of COVID-19. The event occurred 1 month and 29 days after the first dose of the study medication and 27 days after the last dose. The event was considered unrelated to the study medication in agreement with the Investigator's assessment.

### B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	11/02/2020	Blood pressure measurement	114/89 mmHg	
7	11/09/2020	Body temperature	96.8 °F	
8	11/10/2020	Body temperature	96.9 °F	
9	11/11/2020	Body temperature	97 °F	
10	11/12/2020	Body temperature	96.9 °F	
11	11/02/2020	Heart rate	63 heart beats per minute	
12	11/02/2020	Oxygen saturation	95 percent	FDA-CBER-2022-1614-4433558

13	11/03/2020	Oxygen saturation	91 percent
14	11/04/2020	Oxygen saturation	91 percent
15	11/05/2020	Oxygen saturation	95 percent
16	11/06/2020	Oxygen saturation	96 percent
17	11/07/2020	Oxygen saturation	97 percent
18	11/08/2020	Oxygen saturation	99 percent
19	11/09/2020	Oxygen saturation	97 percent
20	11/10/2020	Oxygen saturation	99 percent
21	11/11/2020	Oxygen saturation	99 percent
22	11/12/2020	Oxygen saturation	100 percent
23	11/02/2020	Respiratory rate	15 breaths per minute
24	11/02/2020	SARS-CoV-2 test	Positive
		Nasopharyngeal swab	

## C4. DIAGNOSIS FOR USE (Continued)

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

## C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

3) MIRENA (LEVONORGESTREL) --/--/2018 to ongoing

## 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.	10/02/2020 to 10/02/2020	Blinded	Blinded

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

A. PATIENT INFORMATION			
1. Patient Identifier US3802034	2. Age at Time of Event: 70 Years or Date of Birth: (b) (6)/1950	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 type="checkbox"/> Death: _____ (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) 11/05/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) SYMPTOMATIC COVID 19 [COVID-19]  Case Description: This 70-year-old, White, female subject (US3802034) 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 the non-serious event of symptomatic COVID 19.  The subject's medical history, as provided by the investigator, included right foot fracture, frequent urinary tract infection, asthma, postmenopausal, hypertension, acid reflux, headache, and general muscle pain. Concomitant continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 11/05/2020 Blood pressure measurement (continued) #2 11/05/2020 Body temperature 98.5 °F #3 11/06/2020 Body temperature 97.4 °F #4 11/07/2020 Body temperature 97.4 °F #5 11/08/2020 Body temperature 97.6 °F #6 11/09/2020 Body temperature 97.9 °F continued in additional info section...			
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, (Continued) #2 --/--/2005 to --/--/2005 Historical Condition, (Continued) #3 --/--/2010 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. 08/25/2020 to 08/25/2020	
#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) METHYLPREDNISOLONE (METHYLPREDNISOLONE) 10/29/2020 to 11/02/2020 continued in additional info section...			
G. ALL MANUFACTURERS			
1. Contact Office (and Manufacturing Site for Devices)		2. Phone Number	
Name ModernaTX, Inc. David Martin Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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) 11/20/2020	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 type="checkbox"/> Follow-up # _____			
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) COVID-19		
E. INITIAL REPORTER			
1. Name and Address Dr. JUDITH MARTIN Dept: Children's Hospital of Pittsburgh 3420 FIFTH AVE PITTSBURGH, PA 15213 UNITED STATES			
Phone # (b) (6)	Email Address (b) (6) @chp.edu		
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)

medications reported included methylprednisolone, hydrochlorothiazide, colecalciferol, famotidine, albuterol sulfate, flu vaccine, amoxicillin, and ibuprofen.

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 25 Aug 2020. The subject's last dose of study drug prior to event onset was on 21 Sep 2020.

On 05 Nov 2020, the subject experienced symptomatic COVID 19 with a positive SARS-CoV-2 real-time reverse transcriptase polymerase chain reaction nasopharyngeal swab.

From 05 Nov 2020 through 24 Nov 2020, the subject intermittently experienced mild to moderate chills, cough, fatigue, body aches, headache, loss of taste, loss of smell, nasal congestion, runny nose, and sore throat. She denied shortness of breath, difficulty breathing, muscle aches, nausea, vomiting, or diarrhea. Treatment included oral guaifenesin for congestion, sore throat, and cough.

On 13 Nov 2020, the subject's oxygen saturation was 90%.

On 14 Nov 2020, oxygen saturation returned to normal, 94%

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

The event, symptomatic COVID 19, was reported as resolving.

The investigator assessed the event, symptomatic COVID 19, as not related to study drug and not related to study procedure.

Follow-up received on 20 Nov 2020 included updated event term (previously COVID 19), outcome, event details, action taken with study drug, and concomitant medications.

### Case Comment/Sender's Comment:

Company Comment: This case concerns a 70-year-old, White, female subject who experienced an unexpected event of symptomatic COVID 19. The event occurred 2 months 12 days after the first dose of blinded study vaccine administration and 1 month 16 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	11/05/2020	Blood pressure measurement	135/85 mmHg	
7	11/10/2020	Body temperature	100 °F	
8	11/11/2020	Body temperature	99.8 °F	
9	11/12/2020	Body temperature	98.6 °F	
10	11/13/2020	Body temperature	99.8 °F	
11	11/14/2020	Body temperature	98.1 °F	
12	11/15/2020	Body temperature	99.3 °F	
13	11/16/2020	Body temperature	98.3 °F	
14	11/17/2020	Body temperature	98.1 °F	
15	11/18/2020	Body temperature	97.6 °F	
16	11/19/2020	Body temperature	97.8 °F	

FDA-CBER-2022-1614-4433561

17	11/20/2020	Body temperature	97.4 °F
18	11/21/2020	Body temperature	97.4 °F
19	11/22/2020	Body temperature	97.5 °F
20	11/23/2020	Body temperature	97.3 °F
21	11/24/2020	Body temperature	97.8 °F
22	11/05/2020	Heart rate	79 heart beats per minute
23	11/05/2020	Oxygen saturation	97 percent
24	11/06/2020	Oxygen saturation	98 percent
25	11/07/2020	Oxygen saturation	98 percent
26	11/08/2020	Oxygen saturation	98 percent
27	11/09/2020	Oxygen saturation	97 percent
28	11/10/2020	Oxygen saturation	99 percent
29	11/11/2020	Oxygen saturation	98 percent
30	11/12/2020	Oxygen saturation	98 percent
31	11/13/2020	Oxygen saturation	90 percent
32	11/14/2020	Oxygen saturation	94 percent
33	11/15/2020	Oxygen saturation	97 percent
34	11/16/2020	Oxygen saturation	97 percent
35	11/17/2020	Oxygen saturation	99 percent
36	11/18/2020	Oxygen saturation	98 percent
37	11/19/2020	Oxygen saturation	98 percent
38	11/20/2020	Oxygen saturation	98 percent
39	11/21/2020	Oxygen saturation	97 percent
40	11/22/2020	Oxygen saturation	98 percent
41	11/23/2020	Oxygen saturation	99 percent
42	11/24/2020	Oxygen saturation	98 percent
43	11/05/2020	Respiratory rate	22 breaths per minute

44 11/05/2020 SARS-CoV-2 test  
Positive  
Nasopharyngeal swab

## B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/2000 Ongoing	Current Condition Asthma	
2	--/--/2005 --/--/2005	Historical Condition Foot fracture	Right
3	--/--/2010 Ongoing	Current Condition Urinary tract infection	Frequent
4	--/--/2010 Ongoing	Current Condition Hypertension	
5	Ongoing	Current Condition Postmenopause	
6	Ongoing	Current Condition Gastroesophageal reflux disease	
7	Ongoing	Historical Condition Headache	
8	Ongoing	Current Condition Myalgia	General

## C4. DIAGNOSIS FOR USE (Continued)

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

## C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

- 2) HYDROCHLOROTHIAZIDE (HYDROCHLOROTHIAZIDE) --/--/2010 to ongoing
- 3) VITAMIN D3 (COLECALCIFEROL) --/--/2000 to ongoing
- 4) PEPCID AC (FAMOTIDINE) --/--/2018 to ongoing
- 5) ALBUTEROL --/--/2000 to ongoing
- 6) ADVIL 12 HOUR (IBUPROFEN) --/--/1990 to ongoing
- 7) FLU VACCINE VII (INFLUENZA VACCINE) 10/12/2020 to 10/12/2020
- 8) AMOXICILLIN (AMOXICILLIN) 10/29/2020 to 11/07/2020

## 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.	09/21/2020 to 09/21/2020	Blinded	Blinded



**MEDWATCH**

3500A Facsimile

For use by user-facilities,  
importers, distributors and manufacturers  
for MANDATORY reporting

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

Page 1 of 3

A. PATIENT INFORMATION			
1. Patient Identifier US3412300	2. Age at Time of Event: 59 Years or Date of Birth: (b) (6)/1960	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 265.0 lbs or 120.2 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"/> 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) 11/02/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) SYMPTOMATIC COVID -19 [COVID-19]			
Case Description: This 59-year-old, White, female subject (US3412300) 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 non-serious symptomatic COVID-19.			
The subject's medical history, as provided by the investigator, included allergic medications - tetracycline and doxycycline, and postmenopausal. No relevant concomitant medications were reported.			
continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates			
#1 11/04/2020 Blood pressure measurement (continued)			
#2 11/02/2020 Body temperature 100.1 °F			
#3 11/04/2020 Body temperature (continued)			
#4 11/05/2020 Body temperature 99.8 °F			
#5 11/06/2020 Body temperature 98.8 °F			
#6 11/07/2020 Body temperature 98.1 °F			
continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/2010 to Ongoing, Current Condition, Menopausal symptoms #2 --/--/2017 to Ongoing, Allergy, Drug hypersensitivity (TETRACYCLINE AND DOXYCYCLINE)			

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. 08/24/2020 to 08/24/2020	
#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)			
G. ALL MANUFACTURERS			
1. Contact Office (and Manufacturing Site for Devices)		2. Phone Number	
Name ModernaTX, Inc. David Martin Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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 type="checkbox"/> Follow-up #			
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) COVID-19		
E. INITIAL REPORTER			
1. Name and Address Dr GREGORY GOTTSCHLICH New Horizons Clinical Research 4260 GLENDALE MILFORD ROAD CINCINNATI, ohio 45242 UNITED STATES			
Phone # (b) (6)	Email Address (b) (6) @velocityclinical.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)

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 24 Aug 2020. The subject's last dose of study drug prior to event onset was on 21 Sep 2020.

On 02 Nov 2020, the subject experienced symptomatic COVID-19. She reported a mild dry cough, headaches, fever of 100.1 degrees Fahrenheit and sniffles after being exposed to a coworker who tested positive on 26 Oct 2020. Subject denied shortness of breath, difficulty breathing, nausea, vomiting, diarrhea, fatigue, nasal congestion, sore throat, body aches, myalgia, chills, loss of taste or smell.

On 04 Nov 2020, a SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab was positive. The subject's vital signs included temperature 37.7 degrees Celsius, pulse 84 beats/min, respiratory rate 16 breaths/min, blood pressure 142/80 mmHg. The subject reported a mild fever. No treatment information was reported by the investigator.

On 10 Nov 2020, the subject's vital signs included oxygen saturation 85%.

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

The event, symptomatic COVID-19, was considered recovering.

The investigator assessed the event, symptomatic COVID-19, as not related to study drug and not related to study procedure.

Follow-up received on 19 Nov 2020 included updated symptom log, severity assessment, event term updated to symptomatic COVID-19 (previously COVID-19), outcome, action taken and case narrative.

### Case Comment/Sender's Comment:

This case concerns a 59-year-old female subject who experienced an unexpected event of symptomatic COVID-19. The event occurred 1 month 13 days after the second dose of blinded study medication administration. The event was considered unrelated to the blinded study medication in agreement with the Investigator, noting the subject's exposure to a coworker who tested positive for COVID-19.

### B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	11/04/2020	Blood pressure measurement	142/80 mmHg	
3	11/04/2020	Body temperature	37.7 degree Celsius	
7	11/08/2020	Body temperature	99.9 °F	
8	11/09/2020	Body temperature	99.1 °F	
9	11/10/2020	Body temperature	99.1 °F	
10	11/11/2020	Body temperature	100.0 °F	
11	11/12/2020	Body temperature	98.7 °F	
12	11/13/2020	Body temperature	97.7 °F	
13	11/14/2020	Body temperature	97.1 °F	
14	11/15/2020	Body temperature	98.7 °F	
15	11/16/2020	Body temperature	98.7 °F	
16	11/17/2020	Body temperature	97.6 °F	FDA-CBER-2022-1614-4433565

17	11/04/2020	Heart rate	84 heart beats per minute
18	11/05/2020	Oxygen saturation	97 percent
19	11/06/2020	Oxygen saturation	95 percent
20	11/07/2020	Oxygen saturation	95 percent
21	11/08/2020	Oxygen saturation	95 percent
22	11/09/2020	Oxygen saturation	95 percent
23	11/10/2020	Oxygen saturation	85 percent
24	11/11/2020	Oxygen saturation	95 percent
25	11/12/2020	Oxygen saturation	95 percent
26	11/13/2020	Oxygen saturation	98 percent
27	11/14/2020	Oxygen saturation	95 percent
28	11/15/2020	Oxygen saturation	95 percent
29	11/16/2020	Oxygen saturation	95 percent
30	11/17/2020	Oxygen saturation	95 percent
31	11/04/2020	Respiratory rate	16 breaths per minute
32	11/04/2020	SARS-CoV-2 test Positive Nasopharyngeal Swab	

## C4. DIAGNOSIS FOR USE (Continued)

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

## 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.	09/21/2020 to 09/21/2020	Blinded	Blinded

**MEDWATCH**

3500A Facsimile

For use by user-facilities,  
importers, distributors and manufacturers  
for MANDATORY reporting

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

Page 1 of 5

A. PATIENT INFORMATION			
1. Patient Identifier US3412304	2. Age at Time of Event: 70 Years or Date of Birth: (b) (6)/1950	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"/> 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) 11/03/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) COVID-19 [COVID-19]			
Case Description: This 70 year-old, White, male, subject (US3412304) 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 the non-serious event of COVID-19.			
The subject's medical history, as provided by the investigator, included allergic rhinitis-shrimp, hyperglycemia, type II diabetes, hyperlipidemia, hypertension, gastroesophageal reflux disease, and osteoarthritis of the left foot and lower back. Concomitant medications reported included continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates			
#1 11/03/2020 Body temperature 99.9 °F			
#2 11/05/2020 Body temperature (continued)			
#3 11/06/2020 Body temperature 97.5 °F			
#4 11/07/2020 Body temperature 98.9 °F			
#5 11/09/2020 Body temperature 99.2 °F			
#6 11/10/2020 Body temperature 98.9 °F			
continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/1955 to Ongoing Current Condition, (Continued) #2 --/--/1955, Allergy, Food allergy (Continued) #3 --/--/2000 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. 08/24/2020 to 08/24/2020	
#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) OZEMPIC (SEMAGLUTIDE) 09/08/2020 to ongoing			
2) ALTACE (RAMIPRIL) --/--/2012 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 Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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) 11/24/2020	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 type="checkbox"/> Follow-up # _____			
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) COVID-19		
E. INITIAL REPORTER			
1. Name and Address Dr. GREGORY GOTTSCHLICH New Horizons Clinical Research 4260 GLENDALE MILFORD ROAD CINCINNATI, Ohio 45242 UNITED STATES			
Phone # (b) (6)	Email Address (b) (6) @velocityclinical.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)

semaglutide, ramipril, influenza vaccine, acetylsalicylic acid, glucosamine, glibenclamide/metformin hydrochloride, meloxicam, vitamin not otherwise specified, omeprazole, and rosuvastatin calcium.

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 24 Aug 2020. The subject's last dose of study drug prior to event onset was on 21 Sep 2020.

On 03 Nov 2020, the subject experienced COVID-19. He started feeling fatigued and feverish with body temperature 99.9 degrees Fahrenheit (F).

On 05 Nov 2020, subject had a real-time reverse transcriptase polymerase chain reaction nasopharyngeal SARS-CoV-2 test performed with a positive result.

From 03 Nov 2020 to 26 Nov 2020, the subject reported COVID-19 symptoms of intermittent mild to severe cough, shortness of breath, fatigue, muscle aches, body aches, headache, nasal congestion, runny nose and sore throat. The subject denied experiencing chills, difficulty breathing, loss of taste, loss of smell, nausea, vomiting or diarrhea.

From 27 Nov 2020 to 28 Nov 2020, the subject experienced no symptoms.

From 06 Nov 2020 to 28 Nov 2020, oxygen saturation was ranged from 92% to 98%, and body temperature was ranged from 96.5 F to 100.6 F.

On 13 Nov 2020, the subject received treatment of oral dextromethorphan/guaifenesin.

On 16 Nov 2020, the subject received treatment of oral pseudoephedrine.

Action taken with study drug was not applicable. The subject had received both doses of study medication prior to event onset.

The events, COVID-19, was considered resolving.

The investigator assessed the event, COVID-19, as not related to study drug or study procedure.

Follow-up received on 17 Nov 2020 and on 19 Nov 2020 included updated event term, action taken with study drug, symptoms, laboratory data and concomitant medication dosing.

Follow-up received on 24 Nov 2020 included updated concomitant treatment medications and COVID-19 assessment symptoms log.

### Case Comment/Sender's Comment:

Company Comment: This case concerns a 70 year-old White, male, subject with medical history of hypertension and type II diabetes, who experienced an unexpected event of COVID-19. The event occurred 2 months 11 days after the first dose of blinded study vaccine administration and 1 months 14 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
2	11/05/2020	Body temperature	37.1 degree Celsius	
7	11/11/2020	Body temperature	98.4 °F	
8	11/12/2020	Body temperature	97.9 °F	
9	11/13/2020	Body temperature	100.6 °F	
10	11/14/2020	Body temperature	98.7 °F	
11	11/15/2020	Body temperature	98.7 °F	FDA-CBER-2022-1614-4433568

12	11/16/2020	Body temperature	97.5 °F
13	11/17/2020	Body temperature	98.4 °F
14	11/18/2020	Body temperature 100.1 in the evening	97.9 °F
15	11/19/2020	Body temperature	97.1 °F
16	11/20/2020	Body temperature	97.6 °F
17	11/21/2020	Body temperature	97.3 °F
18	11/22/2020	Body temperature	97.9 °F
19	11/23/2020	Body temperature	97.1 °F
20	11/25/2020	Body temperature	98.2 °F
21	11/26/2020	Body temperature	97.5 °F
22	11/27/2020	Body temperature	96.8 °F
23	11/28/2020	Body temperature	96.5 °F
24	11/06/2020	Oxygen saturation	94 percent
25	11/07/2020	Oxygen saturation	92 percent
26	11/09/2020	Oxygen saturation	95 percent
27	11/10/2020	Oxygen saturation	92 percent
28	11/11/2020	Oxygen saturation	94 percent
29	11/12/2020	Oxygen saturation	95 percent
30	11/13/2020	Oxygen saturation	93 percent
31	11/14/2020	Oxygen saturation	97 percent
32	11/15/2020	Oxygen saturation	93 percent
33	11/16/2020	Oxygen saturation	93 percent
34	11/17/2020	Oxygen saturation	93 percent
35	11/18/2020	Oxygen saturation	96 percent
36	11/19/2020	Oxygen saturation	93 percent
37	11/20/2020	Oxygen saturation	98 percent

FDA-CBER-2022-1614-4433569

38	11/21/2020	Oxygen saturation	97 percent
39	11/22/2020	Oxygen saturation	95 percent
40	11/23/2020	Oxygen saturation	96 percent
41	11/25/2020	Oxygen saturation	97 percent
42	11/26/2020	Oxygen saturation	97 percent
43	11/27/2020	Oxygen saturation	96 percent
44	11/28/2020	Oxygen saturation	98 percent
45	11/05/2020	SARS-CoV-2 test Positive nasopharyngeal swab	OTHER

## B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1955 Ongoing	Current Condition Rhinitis allergic	Shrimp
2	--/--/1955 Ongoing	Allergy Food allergy	ALLERGIC RHINITIS
3	--/--/2000 Ongoing	Current Condition Type 2 diabetes mellitus	
4	--/--/2010 Ongoing	Current Condition Hyperlipidaemia	
5	--/--/2010 Ongoing	Current Condition Gastroesophageal reflux disease	
6	--/--/2010 Ongoing	Current Condition Hyperglycaemia	
7	--/--/2012 Ongoing	Current Condition Hypertension	
8	--/--/2012 Ongoing	Current Condition Osteoarthritis	left
9	--/--/2012 Ongoing	Current Condition Spinal osteoarthritis	Lower back

## C4. DIAGNOSIS FOR USE (Continued)

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

FDA-CBER-2022-1614-4433570

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

## C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

- 3) INFLUENZA VACCINE (INFLUENZA VACCINE) 10/10/2020 to 10/10/2020
- 4) ASPIRIN [ACETYLSALICYLIC ACID] (ASPIRIN [ACETYLSALICYLIC ACID]) --/--/2012 to ongoing
- 5) GLUCOSAMINE (GLUCOSAMINE) --/--/2012 to ongoing
- 6) GLUCOVANCE [GLIBENCLAMIDE;METFORMIN HYDROCHLORIDE] (GLIBENCLAMIDE, METFORMIN HYDROCHLORIDE) --/--/2012 to ongoing
- 7) MOBIC (MELOXICAM) --/--/2015 to ongoing
- 8) MULTIVITAMIN [VITAMINS NOS] (MULTIVITAMIN [VITAMINS NOS]) --/--/2014 to ongoing
- 9) OMEPRAZOLE (OMEPRAZOLE) --/--/2014 to ongoing
- 10) CRESTOR (ROSUVASTATIN CALCIUM) --/--/2010 to ongoing

## 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.	09/21/2020 to 09/21/2020	Blinded	Blinded



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

A. PATIENT INFORMATION			
1. Patient Identifier US3162006	2. Age at Time of Event: 75 Years or Date of Birth: (b) (6)/1945	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 150.0 lbs or 68.0 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"/> Disability or Permanent Damage <input type="checkbox"/> Life-threatening <input type="checkbox"/> Congenital Anomaly/Birth Defect <input checked="" 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) 11/09/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) ACUTE RENAL FAILURE [Acute renal failure] SYMPTOMATIC COVID-19 [COVID-19]  Case Description: This 75-year-old, White, female subject (US3162006) 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 acute renal failure and the non-serious event of COVID-19.  The subject's medical history, as provided by the investigator, included hypertension, hyperlipidemia, restless leg syndrome, osteoporosis and sciatica (bilateral legs). continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 11/11/2020 Aspartate aminotran (continued) #2 11/12/2020 Blood albumin (continued) #3 11/11/2020 Blood chloride (continued) #4 11/11/2020 Blood creatine phos (continued) #5 11/11/2020 Blood creatinine (continued) #6 11/12/2020 Blood creatinine (continued) continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/1990 to Ongoing Current Condition, (Continued) #2 --/--/2014 to Ongoing Current Condition, (Continued) #3 --/--/2014 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. HYDROCHLOROTHIAZIDE (HYDROCHLOROTHIAZIDE)			
2. Dose, Frequency & Route Used		3. Therapy Dates (if unknown, give duration) from/to (or best estimate)	
#1. Blinded, Information withheld.		#1. 07/27/2020 to 07/27/2020	
#2. 12.5 milligram, qd, Oral		#2. 09/--/2019 to 11/11/2020	
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. Hypertension (Hypertension)		#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) LOSARTAN POTASSIUM (LOSARTAN POTASSIUM) 10/--/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 Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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) 11/27/2020		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 type="checkbox"/> Follow-up #			
9. Manufacturer Report Number (b) (6)		8. Adverse Event Term(s) Acute renal failure, COVID-19	
E. INITIAL REPORTER			
1. Name and Address JUDITH KIRSTEIN Advanced Clinical Research - Rancho Paseo 264 N HIGHLAND SPRINGS AVE, SUITE 4 BANNING, CA 92220 UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @velocityclinical.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)**

Concomitant medications reported included influenza vaccine, varicella zoster vaccine RGE (CHO), losartan potassium, carvedilol, rosuvastatin, gabapentin, ropinirole, venlafaxine, ascorbic acid, pantoprazole and acetylsalicylic acid. Other suspect medications include hydrochlorothiazide.

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 27 Jul 2020. The subject's last dose of study drug prior to event onset was on 24 Aug 2020.

On 09 Nov 2020, the subject experienced COVID-19. From 09 Nov 2020 through 20 Nov 2020, she experienced the symptoms of mild to moderate cough, fatigue, body aches, shortness of breath headache, diarrhea and nasal congestion. The subject denied symptoms of chills, difficult breathing, muscle aches, new loss of taste or smell, runny nose, nausea, vomiting, and sore throat.

On 10 Nov 2020, the subject was seen for an illness visit and a SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab was positive for COVID-19. Treatment included codeine phosphate/guaifenesin.

On 11 Nov 2020 at 10:00, she presented to the emergency room (ER) with dizziness. The subject was lightheaded and too weak to stand up and was taken to the ER. She was found to have acute renal failure. She reported that she had gone to the airport on that day to pick up her friend and had a long wait. When her friend arrived and the subject went to open the trunk of the car, she reported that she felt very dizzy and that she fell twice. She did not pass out or have any loss of consciousness. She was advised to go to the emergency room (ER) by the paramedics. In the ER they found that she was positive for COVID-19. The subject denied any known exposure to COVID-19 or any known contact with anybody with COVID-19. She stated that for the past week or so she had not been eating as well and that she had been drinking fluids. In the ER, orthostatics were checked which were negative. She was given 1 L normal saline. The subject was asymptomatic and was not hypoxic. She was evaluated by physical therapy and did well and had no further acute events. The subject's blood urea nitrogen (BUN) was 37 mg/dl (5-25) and creatinine was 2.2 mg/dl (0.5-1.4). Other laboratory results included chloride 93 mmol/l (98-107), glucose 113 mg/dl (70-110), aspartate aminotransferase 45 u/l (15-41), creatine kinase myocardial band (CK-MB) 4.2 ng/ml (0.5-3.6), troponin <0.02 ng/ml (0.01-0.50), glomerular filtration rate African American 26 ml/min/1.73\_m2 and glomerular filtration rate non-African American 22 ml/min/1.73\_m2. She also had hyponatremia 128 mmol/l (135-145), which resolved after hydration with normal saline. The subject did not need oxygen since all oxygen saturations readings were 93% or greater. A chest x-ray anterior posterior view was normal with no acute cardiopulmonary disease. A renal ultrasound showed no hydronephrosis or no acute abnormalities of the kidneys. A computed tomography of the head without contrast showed normal sinuses, no acute skull fracture or intracranial hemorrhage, no acute cerebral infarction or intracranial mass and no acute findings. Losartan and hydrochlorothiazide were held. Treatment included ceftriaxone sodium, dexamethasone, azithromycin, ascorbic acid, cholecalciferol, heparin, zinc sulfate, thiamine and meclizine.

On 12 Nov 2020, the subject was discharged. On the day of discharge chest x-ray posterior anterior view showed no acute cardiopulmonary abnormality. Treatment included acetaminophen. Medical records upon discharge indicated that the subject was diagnosed with acute renal failure and asymptomatic COVID-19. However, the subject had a bad cough and was treated, therefore, per the investigator, the diagnosis should have been symptomatic COVID-19. The subject's physician attributed her renal failure to hydrochlorothiazide which was stopped after conferring with her primary care physician. On the following day, her creatinine was 1.2 mg/dl, BUN of 27 mg/dl, albumin 3.3 g/dl (3.5-5.0), glucose 113 mg/dl (70-110), glomerular filtration rate African American 53 ml/min/1.73\_m2, glomerular filtration rate non-African American 44 ml/min/1.73\_m2, and sodium was improved to 134 mmol/l. She felt clinically well.

Discharge diagnosis included 1. Acute renal failure resolved, 2. Hyponatremia, improved, 3. Hypertension, 4. GERD, 5. Hyperlipidemia, 6. Restless leg syndrome, 7. Depression and 8. Asymptomatic COVID-19 infection.

There was no action taken with study drug in response to the event of COVID-19. The action taken with study drug in response to the event of acute renal failure was reported as not applicable.

The event, acute renal failure, was reported as resolved on 12 Nov 2020. The event, COVID-19, was reported as resolved on 27 Nov 2020.

The investigator assessed the events, COVID-19 and acute renal failure as not related to study drug and not related to the study procedure.

Follow-up information received on 19 Nov 2020 and 20 Nov 2020, included relatedness to study drug procedure for the event symptomatic Covid-19, action taken, concomitant medications, treatment medications and symptoms. Additionally, a discharge summary provided updated laboratory test details, diagnostic results and course of illness.

FDA-CBER-2022-1614-4433573

Follow-up information received on 27 Nov 2020 included event end date and outcome for event, COVID-19.

## Case Comment/Sender's Comment:

Company Comment: This case concerns a 75-year-old, White, female subject with medical history of hypertension, who experienced an unexpected event of acute renal failure and the non-serious event of COVID-19. The serious event occurred 3 months 16 days after the first dose of blinded study vaccine administration and 2 months 19 days after the last dose administration. The events were considered unrelated to the study vaccine in agreement with the Investigator's assessment. The event of acute renal failure was attributed to the subject's concomitant medication, hydrochlorothiazide.

## B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	11/11/2020	Aspartate aminotransferase increased	45 U/L	41 15
2	11/12/2020	Blood albumin	3.3 g/dL	5.0 3.5
3	11/11/2020	Blood chloride	93 millimole per litre	107 98
4	11/11/2020	Blood creatine phosphokinase MB	4.2 ng/mL	3.6 0.5
5	11/11/2020	Blood creatinine	2.2 mg/dl	1.4 0.5
6	11/12/2020	Blood creatinine	1.2 mg/dl	1.4 0.5
7	11/--/2020	Blood creatinine	1.2 mg/dl	1.4 0.5
8	11/11/2020	Blood glucose	113 mg/dl	110 70
9	11/12/2020	Blood glucose	113 mg/dl	110 70
10	11/10/2020	Blood pressure measurement	128/62 mmHg	
11	11/12/2020	Blood sodium	134 millimole per litre	145 135
12	11/11/2020	Blood urea	37 mg/dl	25 5
13	11/12/2020	Blood urea	27 mg/dl	25 5
14	11/15/2020	Blood urea	mg/dl	25 5
15	11/10/2020	Body temperature	96.3 °F	
16	11/13/2020	Body temperature	97.1 °F	
17	11/14/2020	Body temperature	98.2 °F	
18	11/15/2020	Body temperature	97.4 °F	
19	11/16/2020	Body temperature	96.5 °F	
20	11/17/2020	Body temperature	98.5 °F	
21	11/18/2020	Body temperature	98.0 °F	
22	11/19/2020	Body temperature	97.9 °F	

FDA-CBER-2022-1614-4433574

23	11/20/2020	Body temperature	98.1 °F
24	11/21/2020	Body temperature	97.9 °F
25	11/22/2020	Body temperature	98.7 °F
26	11/23/2020	Body temperature	98.5 °F
27	11/24/2020	Body temperature	97.2 °F
28	11/25/2020	Body temperature	98.0 °F
29	11/26/2020	Body temperature	98.6 °F
30	11/27/2020	Body temperature	98.8 °F
31	11/11/2020	Chest X-ray Normal	
32	11/11/2020	Chest X-ray normal with no acute cardiopulmonary disease	
33	11/12/2020	Chest X-ray no acute cardiopulmonary abnormality	
34	11/11/2020	Computerised tomogram head showed normal sinuses, no acute skull fracture or intracranial hemorrhage, no acute cerebral infarction or intracranial mass and no acute findings	
35	11/11/2020	Glomerular filtration rate ml/min/1.73_m2	26
36	11/11/2020	Glomerular filtration rate ml/min/1.73_m2	22
37	11/12/2020	Glomerular filtration rate	53
38	11/12/2020	Glomerular filtration rate	44
39	11/10/2020	Heart rate	61 /min
40	11/10/2020	Oxygen saturation	99 percent
41	11/13/2020	Oxygen saturation	99 percent
42	11/14/2020	Oxygen saturation	98 percent
43	11/15/2020	Oxygen saturation	93 percent

FDA-CBER-2022-1614-4433575

44	11/16/2020	Oxygen saturation	99 percent
45	11/17/2020	Oxygen saturation	99 percent
46	11/18/2020	Oxygen saturation	98 percent
47	11/19/2020	Oxygen saturation	100 percent
48	11/20/2020	Oxygen saturation	99 percent
49	11/21/2020	Oxygen saturation	98 percent
50	11/22/2020	Oxygen saturation	94 percent
51	11/23/2020	Oxygen saturation	96 percent
52	11/24/2020	Oxygen saturation	95 percent
53	11/25/2020	Oxygen saturation	96 percent
54	11/26/2020	Oxygen saturation	99 percent
55	11/27/2020	Oxygen saturation	98 percent
56	11/10/2020	Respiratory rate	13 breaths per minute
57	11/10/2020	SARS-CoV-2 test Positive Nasopharyngeal swab	
58	11/11/2020	Troponin	<0.02 ng/mL 0.50 0.01
59	11/11/2020	Ultrasound kidney	
		showed no hydronephrosis or no acute abnormalities of the kidneys	

## B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1990 Ongoing	Current Condition Restless legs syndrome	BILATERAL
2	--/--/2014 Ongoing	Current Condition Hypertension	
3	--/--/2014 Ongoing	Current Condition Hyperlipidaemia	
4	--/--/2014 Ongoing	Current Condition Osteoporosis	

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

5	--/--/2015 Ongoing	Current Condition Sciatica	(BILATERAL LEGS)
---	-----------------------	-------------------------------	------------------

6	--/--/2019 Ongoing	Current Condition Gastritis
---	-----------------------	--------------------------------

## C4. DIAGNOSIS FOR USE (Continued)

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

## C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

- 2) CARVEDILOL (CARVEDILOL) --/--/2014 to ongoing
- 3) ROSUVASTATIN (ROSUVASTATIN) --/--/2014 to ongoing
- 4) GABAPENTIN (GABAPENTIN) --/--/1990 to ongoing
- 5) ROPINIROLE (ROPINIROLE) --/--/2014 to ongoing
- 6) VENLAFAXINE (VENLAFAXINE) 04/--/2018 to ongoing
- 7) VITAMIN C ACID (ASCORBIC ACID) --/--/2018 to ongoing
- 8) ASPIRIN 81 (ACETYLSALICYLIC ACID) 09/--/2019 to ongoing
- 9) PANTOPRAZOLE (PANTOPRAZOLE) --/--/2019 to 11/17/2020
- 10) FLU VACCINE VII (INFLUENZA VACCINE) 10/08/2020 to 10/08/2020
- 11) SHINGRIX (VARICELLA ZOSTER VACCINE RGE (CHO)) 10/08/2020 to 10/08/2020

## 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.	08/24/2020 to 08/24/2020	Blinded	Blinded

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

<b>A. PATIENT INFORMATION</b>			
1. Patient Identifier US3752025	2. Age at Time of Event: 58 Years or Date of Birth: (b) (6)/1962	3. Sex <input checked="" type="checkbox"/> Female <input 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 type="checkbox"/> Death: _____ (mm/dd/yyyy) <input type="checkbox"/> Disability or Permanent Damage			
<input type="checkbox"/> Life-threatening <input type="checkbox"/> Congenital Anomaly/Birth Defect			
<input checked="" 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) 11/08/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) COVID-19 [COVID-19] HYPOTENSION REQUIRING HOSPITALIZATION [Hypotension]  Case Description: This 58-year-old, White, female subject (US3752025) 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 COVID-19 and hypotension requiring hospitalization.  The subject's medical history, as provided by the investigator, included aortic aneurysm, hypercholesterolemia, continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 11/10/2020 Blood pressure measurement (continued) #2 11/10/2020 Body temperature 98.8 °F #3 11/11/2020 Body temperature 98.8 °F #4 11/12/2020 Body temperature 98.3 °F #5 11/13/2020 Body temperature 98.1 °F #6 11/16/2020 Body temperature 97.3 °F continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/1978 to --/--/1978 Procedure, (Continued) #2 --/--/1989 to --/--/1989 Procedure, (Continued) #3 --/--/1989 to --/--/1989 Procedure, (Continued) continued in additional info section...			

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event

<b>C. SUSPECT PRODUCT(S)</b>			
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. 08/10/2020 to 08/10/2020	
#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) CHANTIX (VARENICLINE TARTRATE) 09/21/2020 to 10/21/2020 continued in additional info section...			
<b>G. ALL MANUFACTURERS</b>			
1. Contact Office (and Manufacturing Site for Devices)		2. Phone Number	
Name ModernaTX, Inc. David Martin Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<input type="checkbox"/> Foreign	
4. Date Received by Manufacturer (mm/dd/yyyy) 11/23/2020		<input checked="" type="checkbox"/> Study	
6. If IND, Give Protocol # mRNA-1273-P301		<input type="checkbox"/> Literature	
7. Type of Report (Check all that apply)		<input type="checkbox"/> Consumer	
<input type="checkbox"/> 5-day <input type="checkbox"/> 30-day		<input checked="" type="checkbox"/> Health Professional	
<input type="checkbox"/> 7-day <input type="checkbox"/> Periodic		<input type="checkbox"/> User Facility	
<input type="checkbox"/> 10-day <input type="checkbox"/> Initial		<input type="checkbox"/> Company Representative	
<input type="checkbox"/> 15-day <input type="checkbox"/> Follow-up # _____		<input type="checkbox"/> Distributor	
Combination Product <input type="checkbox"/> Yes		<input type="checkbox"/> Other: _____	
Pre-1938 <input type="checkbox"/> Yes		_____	
OTC Product <input type="checkbox"/> Yes		_____	
9. Manufacturer Report Number (b) (6)		8. Adverse Event Term(s) COVID-19, Hypotension	
<b>E. INITIAL REPORTER</b>			
1. Name and Address Dr. PRIYANTHA WIJewardane Baptist Health Center for Clinical Research Little Rock, Arkansas UNITED STATES			
Phone # (b) (6)		Email Address (b) (6)	
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			



**ADDITIONAL INFORMATION****B5. EVENT DESCRIPTION (Continued)**

asthma, chronic obstructive pulmonary disorder, irritable bowel syndrome, urinary frequency, generalized headaches, arthritis, depression, sleep apnea, endometriosis, diabetes mellitus type II, gastroesophageal reflux disease, laparoscopic hysterectomy for endometriosis, tubal ligation, wisdom tooth extraction, right breast biopsies x4, surgical sterilization/ hysterectomy, anxiety, back surgery x2, tonsillectomy, cholecystectomy. Concomitant medications reported included varenicline tartrate, salbutamol, budesonide/formoterol fumarate, colecalciferol, gabapentin, zolpidem tartrate, metformin, atorvastatin, sertraline hydrochloride, pantoprazole sodium sesquihydrate and insulin lispro.

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 10 Aug 2020. The subject's last dose of study drug prior to event onset was on 21 Sep 2020.

On 09 Oct 2020, the subject was tested for SARS-CoV-2 by real time reverse transcription polymerase chain reaction (RT-PCR) nasopharyngeal swab and was negative.

On 08 Nov 2020, the subject experienced COVID-19. From 08 Nov 2020 through 23 Nov 2020, the subject intermittently experienced mild to severe headache, new loss of taste, new loss of smell, cough, shortness of breath, fatigue, nasal congestion and body aches. She denied chills, difficulty breathing, muscle aches (myalgia), runny nose (rhinorrhea), nausea, vomiting, diarrhea or sore throat.

On 09 Nov 2020, the subject's oxygen saturation was 92%.

On 10 Nov 2020, the subject experienced hypotension and was subsequently hospitalized. The subject was tested for SARS-CoV-2 by RT-PCR nasopharyngeal swab and was positive. Oxygen saturation was 92%. Her blood pressure in the emergency room was 89/66mmHg. Treatment included intravenous (IV) calcium chloride/ potassium chloride/ sodium lactate, IV fentanyl and oral (PO) cyclobenzaprine.

On 11 Nov 2020, oxygen saturation was 94%, and treatment included IV morphine, rectal and PO paracetamol, and PO ketorolac.

On 13 Nov 2020, oxygen saturation was 91%. Treatment included PO naproxen sodium. The subject was discharged from the hospital.

On 16 Nov 2020, oxygen saturation was 95%.

On 17 Nov 2020, oxygen saturation was 93%.

On 18 Nov 2020, oxygen saturation was 97%.

On 23 Nov 2020, body temperature was 96.5 degree Fahrenheit.

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

The event, COVID-19, was considered resolving. The event, hypotension requiring hospitalization, was considered resolved on 13 Nov 2020.

The investigator assessed the events, COVID-19 and hypotension requiring hospitalization, as not related to study drug and not related to study procedure.

Follow up information received on 19 Nov 2020, included updated medical history, symptoms, vital signs.

Follow up information received on 23 Nov 2020 included updated verbatim for COVID-19 (previously symptomatic COVID-19) and event details.

**Case Comment/Sender's Comment:**

Company Comment: This case concerns a 58-year-old, White, female subject with medical history of aortic aneurysm, hypercholesterolemia, asthma, and chronic obstructive pulmonary disorder, who experienced an unexpected events of COVID-19 and hypotension requiring hospitalization. The event symptomatic COVID-19 occurred 2 months 30 days after the first dose of blinded study vaccine administration and 1 months 19 days after the last dose administration. The event hypotension requiring hospitalization occurred 3 months 1 day after the first dose of blinded study vaccine administration and 1 month 21 days after the last dose administration. The events were considered unrelated to the study vaccine in agreement with the Investigator's assessment, FDA-CBER-2022-1614-4433579



noting the patient's comorbid conditions, including diabetes, asthma, and chronic obstructive pulmonary disease, increase her risk for complications from COVID infection.

## B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	11/10/2020	Blood pressure measurement	89/66 mmHg	
7	11/17/2020	Body temperature	97.7 °F	
8	11/18/2020	Body temperature	97.7 °F	
9	11/19/2020	Body temperature	96.7 °F	
10	11/20/2020	Body temperature	97.7 °F	
11	11/21/2020	Body temperature	97.0 °F	
12	11/22/2020	Body temperature	97.8 °F	
13	11/23/2020	Body temperature	96.5 °F	
14	11/09/2020	Oxygen saturation	92 percent	
15	11/10/2020	Oxygen saturation	92 percent	
16	11/11/2020	Oxygen saturation	94 percent	
17	11/12/2020	Oxygen saturation	94 percent	
18	11/13/2020	Oxygen saturation	91 percent	
19	11/16/2020	Oxygen saturation	95 percent	
20	11/17/2020	Oxygen saturation	93 percent	
21	11/18/2020	Oxygen saturation	97 percent	
22	11/19/2020	Oxygen saturation	97 percent	
23	11/20/2020	Oxygen saturation	95 percent	
24	11/21/2020	Oxygen saturation	95 percent	
25	11/22/2020	Oxygen saturation	94 percent	
26	11/23/2020	Oxygen saturation	95 percent	
27	10/09/2020	SARS-CoV-2 test Negative Nasopharyngeal swab		
28	11/10/2020	SARS-CoV-2 test Positive Nasopharyngeal swab		

FDA-CBER-2022-1614-4433580

## B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1978 --/--/1978	Procedure Tonsillectomy	
2	--/--/1989 --/--/1989	Procedure Sterilisation	Surgical/hysterectomy
3	--/--/1989 --/--/1989	Procedure Spinal operation	Associated condition unknown
4	--/--/1989 UNK	Historical Condition Endometriosis	
5	--/--/1989 --/--/1989	Procedure Hysterectomy	Endometriosis
6	--/--/2004 --/--/2004	Procedure Cholecystectomy	Associated condition unknown
7	--/--/2017 --/--/2017	Historical Condition Aortic aneurysm	
8	--/--/2017 Ongoing	Current Condition Gastroesophageal reflux disease	
9	--/--/2019 Ongoing	Current Condition Anxiety	
10	--/--/2019 --/--/2019	Procedure Spinal operation	Associated condition unknown
11	--/--/2020 Ongoing	Current Condition Hypercholesterolaemia	
12	--/--/2020 Ongoing	Current Condition Type 2 diabetes mellitus	
13	Ongoing	Current Condition Asthma	
14	Ongoing	Current Condition Chronic obstructive pulmonary disease	Disorder
15	Ongoing	Current Condition Irritable bowel syndrome	
16	Ongoing	Current Condition Pollakiuria	

17		Procedure Cholecystectomy	
18	Ongoing	Current Condition Headache	Generalized
19	Ongoing	Current Condition Arthritis	
20	Ongoing	Current Condition Depression	
21	Ongoing	Current Condition Sleep apnoea syndrome	
22		Procedure Female sterilisation	
23		Procedure Tooth extraction	Wisdom
24		Procedure Biopsy breast	Right X4

## C4. DIAGNOSIS FOR USE (Continued)

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

## C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

- 2) ALBUTEROL [SALBUTAMOL] (ALBUTEROL [SALBUTAMOL]) , 90 microgram ongoing
- 3) SYMBICORT (BUDESONIDE, FORMOTEROL FUMARATE) , 160-4.5 microgram ongoing
- 4) CHOLECALCIFEROL (COLECALCIFEROL) ongoing
- 5) GABAPENTIN (GABAPENTIN) ongoing
- 6) AMBIEN (ZOLPIDEM TARTRATE) 10/19/2020 to ongoing
- 7) METFORMIN (METFORMIN) --/--/2020 to ongoing
- 8) ATORVASTATIN (ATORVASTATIN) --/--/2020 to ongoing
- 9) ZOLOFT (SERTRALINE HYDROCHLORIDE) --/--/2019 to ongoing
- 10) PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] (PANTOPRAZOLE SODIUM SESQUIHYDRATE) --/--/2017 to ongoing
- 11) HUMALOG (INSULIN LISPRO) 10/15/2020 to 11/--/2020
- 12) HUMALOG (INSULIN LISPRO) 11/--/2020 to ongoing

## 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.	09/21/2020 to 09/21/2020	Blinded	Blinded

**MEDWATCH**

3500A Facsimile

For use by user-facilities,  
importers, distributors and manufacturers  
for MANDATORY reporting

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

Page 1 of 5

A. PATIENT INFORMATION			
1. Patient Identifier US3272144	2. Age at Time of Event: 29 Years or Date of Birth: (b) (6)/1991	3. Sex <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight 314.4 lbs or 142.6 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"/> Disability or Permanent Damage <input type="checkbox"/> Life-threatening <input type="checkbox"/> Congenital Anomaly/Birth Defect <input checked="" 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) 11/02/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) COVID 19 ILLNESS [COVID-19]  Case Description: This 29-year-old, White, male subject (US3272144), 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 COVID-19 illness.  The subject's medical history, as provided by the investigator, included insomnia, gastroesophageal reflux disease, seasonal allergies, vasectomy, hemorrhoidectomy, wheat allergy, severe obesity, hemorrhoids and cat allergy. Concomitant medications reported included clonazepam, continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 11/04/2020 Blood pressure measurement (continued) #2 11/04/2020 Body temperature 98.4 °F #3 11/05/2020 Body temperature 98.2 °F #4 11/06/2020 Body temperature 98.8 °F #5 11/07/2020 Body temperature 101.1 °F #6 11/08/2020 Body temperature 101.6 °F continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/1995 to Ongoing Current Condition, (Continued) #2 --/--/1995 to Ongoing Allergy, (Continued) #3 --/--/2013 to --/--/2016 Historical Condition, (Continued) continued in additional info section...			

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event

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. 08/14/2020 to 08/14/2020	
#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) CLONAZEPAM (CLONAZEPAM) --/--/2017 to ongoing			
2) OMEPRAZOLE (OMEPRAZOLE) --/--/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 Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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 # 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 type="checkbox"/> Follow-up #			
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) COVID-19		
E. INITIAL REPORTER			
1. Name and Address Dr. ADAM BROSZ Meridian Clinical Research (Grand Island, Nebraska) 2444 W. FAIDLEY AVE GRAND ISLAND, NE 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	

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

## ADDITIONAL INFORMATION

### B5. EVENT DESCRIPTION (Continued)

omeprazole, cetirizine, and vitamin 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 14 Aug 2020. The subject's last dose of study drug prior to event onset was on 11 Sep 2020.

On 02 Nov 2020, the subject experienced COVID-19 illness with a positive SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab on 04 Nov 2020 and radiographical evidence on 13 Nov 2020. Treatment included paracetamol.

From 02 Nov 2020 through 22 Nov 2020, the subject intermittently experienced mild to severe chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, loss of taste, loss of smell, nasal congestion, runny nose (rhinorrhea), nausea, diarrhea, and sore throat. He denied experiencing vomiting.

From 07 Nov 2020 through 10 Nov 2020, the subject had an elevated temperature of 100.6 to 101.6 degrees Fahrenheit; returned to normal on 11 Nov 2020. Treatment included pseudoephedrine.

On 11 Nov 2020, his symptoms worsened, and he contacted his primary care physician and was given a prescription cough syrup. Oxygen saturation was 92%.

On 12 Nov 2020, the subject was admitted to the hospital for general observation. He was stable and no oxygen support was needed. Treatment included enoxaparin. Oxygen saturation was 92%.

On 13 Nov 2020, the subject was discharged from the hospital. Treatment included cough drops. Temperature was 101.6 degrees Fahrenheit.

On 14 Nov 2020, oxygen saturation was 92% and temperature was 100.2 degrees Fahrenheit.

On 16 Nov 2020, subject experienced bronchospasms, hypoxia and oxygen saturation around 80% with shortness of breath so he returned to the emergency department. He was admitted to the hospital. He was on 2 liters of oxygen via a nasal cannula at night but was on room air while awake during the day. He experienced repeated bouts of diarrhea. Temperature was 97.0 degrees Fahrenheit, oxygen saturation at 91%. Treatment included remdesivir, dexamethasone and tramadol.

On 17 Nov 2020, treatment included remdesivir, dexamethasone, levofloxacin and lactobacillus.

On 18 Nov 2020, treatment included vitamin C, vitamin D3 and zinc sulfate. Oxygen saturation was 95%.

On 19 Nov 2020, he was discharged. At the time of discharge his oxygen saturations on room air remained at 98%-99%. He was sent home with a prescription for zinc, vitamin D3, ascorbic acid and an albuterol inhaler. He was told to follow-up with his primary care physician as needed.

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

The event, COVID-19 illness, was considered resolved on 29 Nov 2020.

The investigator assessed the event, COVID-19 illness, as not related to study drug and not related to study procedure.

Follow-up received on 19 Nov 2020, 20 Nov 2020 and 23 Nov 2020 included updated lab values, treatment medications, hospital admission date, updated action taken and outcome.

Follow-up received on 01 Dec 2020 included updated end date, outcome, vital signs and symptom log.

### Case Comment/Sender's Comment:

This case concerns a 29-year-old male subject who experienced an unexpected event of COVID-19 illness. The event occurred 1 month 23 days after the second dose of blinded study medication administration. The event was considered unrelated to the blinded study medication in agreement with the Investigator.

### B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	FDA-CBER-2022-1614-4433584
				Normal High / Low

1	11/04/2020	Blood pressure measurement	128/79 mmHg
7	11/09/2020	Body temperature	100.6 °F
8	11/10/2020	Body temperature	100.6 °F
9	11/11/2020	Body temperature	98.3 °F
10	11/12/2020	Body temperature	98.7 °F
11	11/13/2020	Body temperature	101.6 °F
12	11/14/2020	Body temperature	100.2 °F
13	11/15/2020	Body temperature	100.0 °F
14	11/16/2020	Body temperature	97.0 °F
15	11/17/2020	Body temperature	36.6 °C
16	11/18/2020	Body temperature	98.7 °F
17	11/19/2020	Body temperature	97.8 °F
18	11/20/2020	Body temperature	96.8 °F
19	11/21/2020	Body temperature	98.0 °F
20	11/29/2020	Body temperature	98.4 °F
21	11/30/2020	Body temperature	98.6 °F
22	11/04/2020	Heart rate	87 heart beats per minute
23	11/04/2020	Oxygen saturation	97 percent
24	11/05/2020	Oxygen saturation	97 percent
25	11/06/2020	Oxygen saturation	96 percent
26	11/07/2020	Oxygen saturation	94 percent
27	11/08/2020	Oxygen saturation	95 percent
28	11/09/2020	Oxygen saturation	95 percent
29	11/10/2020	Oxygen saturation	94 percent
30	11/11/2020	Oxygen saturation	92 percent
31	11/12/2020	Oxygen saturation	92 percent
32	11/13/2020	Oxygen saturation	93 percent

FDA-CBER-2022-1614-4433585

33	11/14/2020	Oxygen saturation	92 percent
34	11/15/2020	Oxygen saturation	95 percent
35	11/16/2020	Oxygen saturation	80 percent
		91	
36	11/17/2020	Oxygen saturation	93 percent
37	11/18/2020	Oxygen saturation	95 percent
38	11/19/2020	Oxygen saturation	99 percent
39	11/20/2020	Oxygen saturation	96 percent
40	11/21/2020	Oxygen saturation	97 percent
41	11/29/2020	Oxygen saturation	97 percent
42	11/30/2020	Oxygen saturation	96 percent
43	11/04/2020	Respiratory rate	20 breaths per minute
44	11/04/2020	SARS-CoV-2 test Positive Nasopharyngeal swab	

## B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1995 Ongoing	Current Condition Gastroesophageal reflux disease	
2	--/--/1995 Ongoing	Allergy Seasonal allergy	
3	--/--/2013 --/--/2016	Historical Condition Haemorrhoids	
4	--/--/2015 Ongoing	Current Condition Insomnia	
5	--/--/2016 --/--/2016	Procedure Haemorrhoid operation	
6	--/--/2016 Ongoing	Allergy Allergy to animal	cat
7	--/--/2017 Ongoing	Current Condition Obesity	SEVERE

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

8	--/--/2019 --/--/2019	Procedure Vasectomy	
9	--/--/2019 Ongoing	Allergy Food allergy	wheat

## C4. DIAGNOSIS FOR USE (Continued)

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

## C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

3) CETIRIZINE (CETIRIZINE) --/--/2015 to ongoing

4) MULTI-VIT (VITAMINS NOS) --/--/2017 to ongoing

## 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.	09/11/2020 to 09/11/2020	Blinded	Blinded



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

A. PATIENT INFORMATION			
1. Patient Identifier US3802185	2. Age at Time of Event: 53 Years or Date of Birth: (b) (6)/1967	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 type="checkbox"/> Death: _____ (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) 11/11/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) SYMPTOMATIC COVID 19 [COVID-19]			
Case Description: This 53-year-old, (b) (6), female subject (US3802185) 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 the non-serious event of symptomatic COVID 19.			
The subject's medical history, as provided by the investigator, included seasonal allergies, high cholesterol, tonsils removed, gastroesophageal reflux disease, left wrist fracture, allergy related asthma, and basal cell removal. continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 11/11/2020 Blood pressure measurement (continued) #2 11/11/2020 Body temperature 36 °C #3 11/12/2020 Body temperature 98.7 °F #4 11/13/2020 Body temperature 99.5 °F #5 11/14/2020 Body temperature 98.5 °F #6 11/15/2020 Body temperature 99 °F continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pr _____ unction, etc.) Race: (b) (6) #1 --/--/1983 to --/--/1983 Procedure, (Continued) #2 --/--/2005 to --/--/2005 Historical Condition, (Continued) #3 --/--/2010 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. 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) VITAMIN D3 (COLECALCIFEROL) --/--/2015 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 Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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) 11/24/2020	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 type="checkbox"/> Follow-up # _____		
9. Manufacturer Report Number (b) (6)		8. Adverse Event Term(s) COVID-19	
E. INITIAL REPORTER			
1. Name and Address Dr. JUDITH MARTIN Children's Hospital of Pittsburg PITTSBURGH, PA 15213 UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @chp.edu	
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)

Concomitant medications reported included colecalciferol, albuterol sulfate, ascorbic acid, atorvastatin, hydrochlorothiazide, loratadine, norethindrone acetate, fish oil, calcium carbonate/ colecalciferol, omeprazole, and montelukast sodium.

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 12 Oct 2020.

On 11 Nov 2020, the subject experienced COVID 19 with a positive SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab.

From 11 Nov 2020 through 30 Nov 2020, the subject intermittently experienced mild to severe chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, nasal congestion, runny nose (rhinorrhea), and sore throat. She denied experiencing new loss of taste, new loss of smell, nausea, vomiting, or diarrhea. Treatment included paracetamol.

On 14 Nov 2020 and on 15 Nov 2020, the subject's oxygen saturation was 89% and 92%, respectively.

Study drug action taken listed as not applicable, as the subject had already received both scheduled doses.

The event, symptomatic COVID 19, was reported as not resolved.

The investigator assessed the event, symptomatic COVID 19, as not related to study drug and not related to study procedure.

Follow-up received on 24 Nov 2020 included treatment information and additional vital signs assessments.

### Case Comment/Sender's Comment:

Company Comment: This case concerns a 53-year-old, (b) (6), female subject with medical history of asthma, who experienced an unexpected event of EVENT. The event occurred 2 months 3 days after the first dose of blinded study vaccine administration and 1 month 1 day 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	11/11/2020	Blood pressure measurement	126/83 mmHg	
7	11/16/2020	Body temperature	99.0 °F	
8	11/17/2020	Body temperature	100.5 °F	
9	11/18/2020	Body temperature	99 °F	
10	11/19/2020	Body temperature	99 °F	
11	11/20/2020	Body temperature	99 °F	
12	11/21/2020	Body temperature	99.1 °F	
13	11/22/2020	Body temperature	98.8 °F	
14	11/23/2020	Body temperature	98.9 °F	
15	11/24/2020	Body temperature	98.9 °F	
16	11/25/2020	Body temperature	99.1 °F	
17	11/26/2020	Body temperature	99.1 °F	

FDA-CBER-2022-1614-4433589

18	11/27/2020	Body temperature	98.6 °F
19	11/28/2020	Body temperature	98.3 °F
20	11/29/2020	Body temperature	98.4 °F
21	11/30/2020	Body temperature	98.1 °F
22	11/11/2020	Heart rate	95 heart beats per minute
23	11/11/2020	Oxygen saturation	97 percent
24	11/12/2020	Oxygen saturation	97 percent
25	11/13/2020	Oxygen saturation	95 percent
26	11/14/2020	Oxygen saturation	89 percent
27	11/15/2020	Oxygen saturation	92 percent
28	11/16/2020	Oxygen saturation	95 percent
29	11/17/2020	Oxygen saturation	95 percent
30	11/18/2020	Oxygen saturation	96 percent
31	11/19/2020	Oxygen saturation	95 percent
32	11/20/2020	Oxygen saturation	95 percent
33	11/21/2020	Oxygen saturation	96 percent
34	11/22/2020	Oxygen saturation	96 percent
35	11/23/2020	Oxygen saturation	96 percent
36	11/24/2020	Oxygen saturation	96 percent
37	11/25/2020	Oxygen saturation	96 percent
38	11/26/2020	Oxygen saturation	96 percent
39	11/27/2020	Oxygen saturation	96 percent
40	11/28/2020	Oxygen saturation	96 percent
41	11/29/2020	Oxygen saturation	96 percent
42	11/30/2020	Oxygen saturation	96 percent
43	11/11/2020	Respiratory rate	20 breaths per minute
44	11/11/2020	SARS-CoV-2 test	FDA-CBER-2022-1614-4433590

Positive  
Nasopharyngeal Swab

## B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1983 --/--/1983	Procedure Tonsillectomy	
2	--/--/2005 --/--/2005	Historical Condition Wrist fracture	Left
3	--/--/2010 Ongoing	Current Condition Blood cholesterol increased	
4	--/--/2010 Ongoing	Current Condition Gastroesophageal reflux disease	
5	--/--/2010 --/--/2010	Procedure Skin neoplasm excision	
6	--/--/2020 Ongoing	Current Condition Asthma	
7	Ongoing	Current Condition Seasonal allergy	

## C4. DIAGNOSIS FOR USE (Continued)

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

## C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

- 2) ALBUTEROL SULFATE (ALBUTEROL SULFATE) --/--/2020 to ongoing
- 3) VITAMIN C (ASCORBIC ACID) 03/--/2020 to ongoing
- 4) ATORVASTATIN (ATORVASTATIN) --/--/2010 to ongoing
- 5) HYDROCHLOROTHIAZIDE (HYDROCHLOROTHIAZIDE) --/--/2015 to ongoing
- 6) CLARITIN [LORATADINE] (LORATADINE) --/--/1975 to ongoing
- 7) NORETHINDRONE ACETATE (NORETHINDRONE ACETATE) --/--/2015 to ongoing
- 8) OMEGA 3 FISH OILS (FISH OIL) --/--/2015 to ongoing
- 9) CALCIUM D3 (CALCIUM CARBONATE, COLECALCIFEROL) --/--/2010 to ongoing
- 10) OMEPRAZOLE (OMEPRAZOLE) --/--/2010 to ongoing
- 11) SINGULAIR (MONTELUKAST SODIUM) --/--/2010 to ongoing

## 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.	10/12/2020 to 10/12/2020	Blinded	Blinded

**MEDWATCH**

3500A Facsimile

For use by user-facilities,  
importers, distributors and manufacturers  
for MANDATORY reporting

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

Page 1 of 3

A. PATIENT INFORMATION			
1. Patient Identifier US3272026	2. Age at Time of Event: 46 Years or Date of Birth: (b) (6)/1974	3. Sex <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight 271.0 lbs or 122.9 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 checked="" type="checkbox"/> Life-threatening <input checked="" type="checkbox"/> Hospitalization - initial or prolonged <input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage (Devices)			
<input checked="" 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) 11/08/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) COVID19 [COVID-19]			
Case Description: This 46-year-old, White, male subject (US3272026) 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 a serious event of COVID19.			
The subject's medical history, as provided by the investigator, included seasonal allergies, vasectomy and bilateral axillary skin tags. Concomitant medications reported included fexofenadine.			
continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates			
#1 11/12/2020 Blood pressure measurement (continued)			
#2 11/13/2020 Blood pressure measurement (continued)			
#3 11/12/2020 Body temperature 97.4 °F			
#4 11/13/2020 Body temperature 98.5 °F			
#5 11/14/2020 Body temperature 101.5 °F			
#6 11/15/2020 Body temperature 98.3 °F			
continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White			
#1 --/--/2002 to --/--/2002, Procedure, Vasectomy			
#2 --/--/2010 to Ongoing, Current Condition, Acrochordon (BILATERAL AXILLARY)			
#3 --/--/2013 to Ongoing, Allergy, Seasonal allergy			

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. 08/01/2020 to 08/01/2020	
#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) FEXOFENADINE (FEXOFENADINE) --/--/2013 to ongoing			
G. ALL MANUFACTURERS			
1. Contact Office (and Manufacturing Site for Devices)		2. Phone Number	
Name ModernaTX, Inc. David Martin Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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) 11/20/2020		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 type="checkbox"/> Follow-up #			
9. Manufacturer Report Number (b) (6)		8. Adverse Event Term(s) COVID-19	
E. INITIAL REPORTER			
1. Name and Address Dr. ADAM BROSZ Meridian Clinical Research (Grand Island, Nebraska) 2444 W. FAIDLEY AVE GRAND ISLAND, NE 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)

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 Aug 2020. The subject's last dose of study drug prior to event onset was on 08 Sep 2020.

On 08 Nov 2020, the subject experienced a life threatening, medically significant event of COVID-19, which caused significant disability. His oxygen saturation was in the 80s%. From 08 Nov 2020 to 22 Nov 2020, the subject intermittently experienced mild to moderate symptoms of chills, cough, shortness of breath, difficult breathing, muscle aches, body aches, headache and fatigue. During this time the subject did not report any of the following symptoms including, new loss of taste and smell, nasal congestion, runny nose, nausea, vomiting, diarrhea and sore throat.

On 09 Nov 2020, a SARS-CoV-2 real-time reverse transcription polymerase chain reaction by nasopharyngeal swab was positive for COVID-19.

On 11 Nov 2020, COVID-19 testing was performed per the subject's primary care physician which resulted positive. The subject was started on steroids.

On 12 Nov 2020, the subject was re-tested during a site visit for SARS-CoV-2 real-time reverse transcription polymerase chain reaction by nasopharyngeal swab which resulted positive for COVID-19.

On 14 Nov 2020, the subject's experienced fever of 101.5 degrees Fahrenheit which dropped to 98.3 degrees Fahrenheit on the following day.

On 16 Nov 2020, the subject condition worsened with severe symptoms of chills, shortness of breath, difficult breathing, fatigue and was directed to the emergency room for sustained hypoxia. Vital signs included oxygen saturation of 78% on room air with a temperature of 103.1 degrees Fahrenheit. The subject was admitted to the intensive care unit and was started on bilevel positive airway pressure with 75% oxygen. Radiograph performed showed evidence of pneumonia. The subject was diagnosed with acute respiratory failure, acute kidney injury, acute respiratory distress syndrome and multifocal pneumonia. Treatment for the event included respiratory albuterol sulfate, oral dexamethasone, intravenous (IV) dexamethasone, IV piperacillin sodium/tazobactam sodium, IV azithromycin, IV ceftriaxone, IV remdesivir, and subcutaneous enoxaparin.

On 18 Nov 2020, the subject's severe symptoms improved to moderate condition; vital signs were oxygen saturation 94% and temperature 100.2 degrees Fahrenheit.

On 22 Nov 2020, the subject's vital signs included oxygen saturation 90% and temperature 98.9 degrees Fahrenheit.

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

The event, COVID19, was reported as not resolved.

The investigator assessed the event, COVID19, as not related to the study drug or study procedure.

Follow-up received on 24 Nov 2020 included testing and event details.

Case Comment/Sender's Comment:

Company Comment: This case concerns a 46-year-old, White, male subject who experienced an unexpected event of COVID19.. The event occurred 3 months 8 days after the first dose of blinded study vaccine administration and 2 months 1 day 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	11/12/2020	Blood pressure measurement	132/83 mmHg	
2	11/13/2020	Blood pressure measurement	mmHg	
7	11/16/2020	Body temperature	103.1 °F	
8	11/18/2020	Body temperature	100.2 °F	FDA-CBER-2022-1614-4433593

9	11/21/2020	Body temperature	98 °F
10	11/22/2020	Body temperature	98.9 °F
11	11/12/2020	Heart rate	84 heart beats per minute
12	11/12/2020	Oxygen saturation	100 percent
13	11/13/2020	Oxygen saturation	97 percent
14	11/14/2020	Oxygen saturation	97 percent
15	11/15/2020	Oxygen saturation	96 percent
16	11/16/2020	Oxygen saturation	78 percent
17	11/18/2020	Oxygen saturation	94 percent
18	11/21/2020	Oxygen saturation	90 percent
19	11/22/2020	Oxygen saturation	90 percent
20	11/12/2020	Respiratory rate	18 breaths per minute
21	11/11/2020	SARS-CoV-2 test Positive	
22	11/12/2020	SARS-CoV-2 test Positive Nasopharyngeal swab	
23	11/16/2020	X-ray  Evidence of pneumonia	

## C4. DIAGNOSIS FOR USE (Continued)

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

## 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.	09/08/2020 to 09/08/2020	Blinded	Blinded



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

A. PATIENT INFORMATION			
1. Patient Identifier US3402194	2. Age at Time of Event: 58 Years or Date of Birth: (b) (6)/1962	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"/> Disability or Permanent Damage <input type="checkbox"/> Life-threatening <input type="checkbox"/> Congenital Anomaly/Birth Defect <input checked="" 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) 11/06/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) COVID-19 [COVID-19]  Case Description: This 58-year-old, White, male subject (US3402194) 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 COVID-19.  The subject's medical history, as provided by the investigator, included type 1 diabetes, peripheral vascular disease and coronary artery disease. Concomitant medications reported included insulin lispro, ticagrelor, atorvastatin and lisinopril. continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 11/13/2020 Blood pressure measurement (continued) #2 11/12/2020 Body temperature 99.3 °F #3 11/13/2020 Body temperature 99.3 °F #4 11/14/2020 Body temperature 99.0 °F #5 11/15/2020 Body temperature 99.0 °F #6 11/16/2020 Body temperature 99 °F continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/1979 to Ongoing, Current Condition, Type 1 diabetes mellitus #2 05/--/2017 to Ongoing, Current Condition, Coronary artery disease  #3 --/--/2018 to Ongoing, Current Condition, Peripheral vascular disorder			

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event

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. 08/02/2020 to 08/02/2020	
#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) ADMELOG (INSULIN LISPRO) --/--/1979 to ongoing			
2) BRILINTA (TICAGRELOR) --/--/2018 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 Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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 # 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 type="checkbox"/> Follow-up # _____		
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) COVID-19		
E. INITIAL REPORTER			
1. Name and Address Dr. FRANK EDER Meridian Clinical Research, LLC 1290 UPPER FRONT STREET BINGHAMTON, NY 13901 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	



## 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 02 Aug 2020. The subject's last dose of study drug prior to event onset was on 02 Sep 2020.

On 06 Nov 2020, the subject experienced COVID-19.

From 06 Nov through 13 Nov 2020, the subject experienced intermittent mild to moderate chills, cough, headache, fatigue, nausea, vomiting and diarrhea.

On 13 Nov 2020, a SARS-CoV-2 real time reverse transcriptase polymerase chain reaction nasopharyngeal swab was positive.

From 15 Nov 2020 to 17 Nov 2020, the subject experienced intermittent mild to moderate cough, shortness of breath, myalgia, body aches, new loss of taste and smell, nausea, vomiting, diarrhea and sore throat.

On 16 Nov 2020, the subject was hospitalized for COVID-19. His oxygen saturation was 83 percent, and he was placed on 6L high-flow oxygen. Treatment for the event included intravenous (IV) ascorbic acid, oral (PO) acetylsalicylic acid, PO and IV glucose, IV heparin, IV dextrose, IV sodium chloride, respiratory albuterol sulfate, PO furosemide, PO paracetamol and IV dexamethasone.

On 17 Nov 2020, the subject's oxygen saturation was 92%. Treatment included IV thiamine.

On 18 Nov 2020, the subject's oxygen saturation was 94%. Treatment included initiation of IV remdesivir. On the same day, all symptoms resolved.

On 22 Nov 2020 and 23 Nov 2020, the subject's oxygen saturation was 92%.

On 24 Nov 2020, the subject's oxygen saturation was 94%.

On 26 Nov 2020, the subject was discharged from the hospital.

On 01 Dec 2020, the subject's oxygen saturation was 90%.

Action taken with study drug dosing was not applicable as the subject had already received both scheduled doses.

The event, COVID-19, was considered resolving.

The investigator assessed the event, COVID-19, as not related to study drug and not related to study procedure.

Follow-up received on 19 Nov 2020 and 23 Nov 2020 included updated event verbatim, start date, outcome, and symptoms.

Follow-up received on 01 Dec 2020 included hospital discharge date, updated onset date, and updated symptoms log.

### Case Comment/Sender's Comment:

This case concerns a 58- year-old, White, male subject with medical history of type 1 diabetes, peripheral vascular disease and coronary artery disease, who experienced an unexpected event of COVID-19. The event occurred 3 months 2 days after the initial dose of blinded study medication administration and 2 months 2 days after the last dose of blinded study medication administration. The event was considered unrelated to the blinded study medication in agreement with the Investigator.

### B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	11/13/2020	Blood pressure measurement	107/65 mmHg	
7	11/17/2020	Body temperature	98.9 °F	
8	11/18/2020	Body temperature	97.3 °F	
9	11/19/2020	Body temperature	98.1 °F	FDA-CBER-2022-1614-4433596

10	11/20/2020	Body temperature	98.1 °F
11	11/21/2020	Body temperature	98.2 °F
12	11/22/2020	Body temperature	98.1 °F
13	11/23/2020	Body temperature	98.1 °F
14	11/24/2020	Body temperature	98.1 °F
15	11/25/2020	Body temperature	98.2 °F
16	11/26/2020	Body temperature	98.2 °F
17	11/27/2020	Body temperature	98.1 °F
18	11/30/2020	Body temperature	98.1 °F
19	12/01/2020	Body temperature	97.6 °F
20	11/13/2020	Heart rate	87 heart beats per minute
21	11/12/2020	Oxygen saturation	96 percent
22	11/13/2020	Oxygen saturation	96 percent
23	11/14/2020	Oxygen saturation	99 percent
24	11/15/2020	Oxygen saturation	94 percent
25	11/16/2020	Oxygen saturation	83 percent
26	11/17/2020	Oxygen saturation	92 percent
27	11/18/2020	Oxygen saturation	94 percent
28	11/19/2020	Oxygen saturation	94 percent
29	11/20/2020	Oxygen saturation	94 percent
30	11/21/2020	Oxygen saturation	94 percent
31	11/22/2020	Oxygen saturation	92 percent
32	11/23/2020	Oxygen saturation	92 percent
33	11/24/2020	Oxygen saturation	94 percent
34	11/25/2020	Oxygen saturation	95 percent
35	11/26/2020	Oxygen saturation	96 percent
36	11/27/2020	Oxygen saturation	99 percent

FDA-CBER-2022-1614-4433597

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

37	11/30/2020	Oxygen saturation	95 percent
38	12/01/2020	Oxygen saturation	90 percent
39	11/13/2020	Respiratory rate	14 breaths per minute
40	11/13/2020	SARS-CoV-2 test Positive Nasopharyngeal swab	

## C4. DIAGNOSIS FOR USE (Continued)

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

## C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

3) ATORVASTATIN (ATORVASTATIN) 05/--/2017 to ongoing

4) LISINOPRIL (LISINOPRIL) 05/--/2017 to ongoing

## 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.	09/02/2020 to 09/02/2020	Blinded	Blinded

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

A. PATIENT INFORMATION			
1. Patient Identifier US3722066	2. Age at Time of Event: 67 Years or Date of Birth: (b) (6)/1952	3. Sex <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight 196.0 lbs or 88.9 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"/> Disability or Permanent Damage <input type="checkbox"/> Life-threatening <input type="checkbox"/> Congenital Anomaly/Birth Defect <input checked="" 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) 11/11/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) POSITIVE COVID 19 [COVID-19]  Case Description: This 67-year-old, white, male subject (US3722066) 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 the event of positive Covid-19.  The subject's medical history, as provided by the investigator, included torn rotator cuff left and right shoulder, hypertension, abdominal hernia, vasectomy, iron deficiency anemia, hypercholesterol, restless leg syndrome, hypothyroidism, gastroesophageal reflux disease, asthma, continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 11/16/2020 Blood pressure measurement (continued) #2 11/16/2020 Body temperature 102.6 °F #3 11/16/2020 Body temperature 98.7 °F #4 11/16/2020 Heart rate 81 minute #5 11/16/2020 Oxygen saturation 87 percent #6 11/16/2020 Oxygen saturation 86 percent continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/1956 to Ongoing Current Condition, (Continued) #2 --/--/1956 to Ongoing Current Condition, (Continued) #3 --/--/1972 to --/--/2017 Historical 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. 08/03/2020 to 08/03/2020	
#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) IPRATROPIUM [IPRATROPIUM BROMIDE] (IPRATROPIUM BROMIDE) --/--/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 Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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) 11/24/2020	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 type="checkbox"/> Follow-up #		
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) COVID-19		
E. INITIAL REPORTER			
1. Name and Address Dr Adam Brosz Meridian Clinical Research Grand Island, Nebraska 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)

seasonal allergies and osteoarthritis in the right knee, hip, bilateral thumbs and shoulders. Concomitant medications reported included ipratropium bromide, amlodipine besilate, montelukast, acetylsalicylic acid, ferrous sulfate, paracetamol, ubidecarenone, colecalciferol, atorvastatin, gabapentin, indapamide, levothyroxine, omeprazole, ropinirole, valsartan and fluticasone propionate.

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 03 Aug 2020. The subject's last dose of study drug prior to event onset was on 28 Aug 2020.

On 11 Nov 2020, the subject experienced the serious event of positive Covid-19. Signs and symptoms from 11 Nov 2020 through 16 Nov 2020, included, severe shortness of breath, severe difficulty breathing, moderate chills, moderate muscle aches (myalgia) and moderate body aches.

On 16 Nov 2020, the subject was scheduled to come to the site for a convalescent visit. The subject thought he had pneumonia and upon arriving the subject stated that he had received a positive SARS-CoV-2 real time polymerase chain reaction by nasopharyngeal swab. Vital signs included temperature 102.6 Fahrenheit, oxygen saturation 87% on room air, pulse 81 beats per minute, respiratory rate 24 beats per minute and blood pressure 155/83 mmHg. The principal investigator advised emergency medical services (EMS) be called for the subject to go to the emergency room (ER). At that time, EMS was called and the subject was transported to the ER and he was admitted to the hospital. Clinical evidence revealed pneumonia.

Action taken with study drug was not applicable as the subject had already received both scheduled doses.

The event, positive Covid-19, was reported as not recovered.

The investigator assessed the event, positive Covid-19 as not related to study drug and not related to study procedure.

Follow-up received on 24 Nov 2020 included updated action taken with study drug, symptoms, event terms and details.

#### Case Comment/Sender's Comment:

Company Comment: This case concerns the 67 year old male subject with medical history of hypertension, iron deficiency anemia, hypercholesterol, hypothyroidism, gastroesophageal reflux disease, asthma, seasonal allergies and osteoarthritis in the right knee, hip, bilateral thumbs and shoulders, who experienced an unexpected event of positive COVID 19. The event positive COVID 19 occurred 3 months 9 days after the first dose of IP and 2 months 15 days after the second dose of IP. The event was considered unrelated to the study medication in agreement with the Investigator's assessment.

### B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	11/16/2020	Blood pressure measurement	155/83 mmHg	
7	11/16/2020	Respiratory rate	24 breaths per minute	
8	11/16/2020	SARS-CoV-2 test Positive Nasopharyngeal swab		

### B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1956 Ongoing	Current Condition Asthma	
2	--/--/1956 Ongoing	Current Condition Seasonal allergy	

3	--/--/1972 --/--/2017	Historical Condition Rotator cuff syndrome	left shoulder
4	--/--/1972 --/--/2015	Historical Condition Rotator cuff syndrome	right shoulder
5	--/--/1988 Ongoing	Procedure Vasectomy	
6	--/--/1990 Ongoing	Current Condition Hypercholesterolaemia	
7	--/--/1990 Ongoing	Current Condition Hypothyroidism	
8	--/--/1990 Ongoing	Current Condition Osteoarthritis	right knee and hip, bilateral thumbs and shoulders
9	07/--/1990 Ongoing	Current Condition Gastroesophageal reflux disease	
10	--/--/1995 Ongoing	Current Condition Iron deficiency anaemia	
11	--/--/2005 Ongoing	Current Condition Hypertension	
12	--/--/2006 --/--/2006	Historical Condition Abdominal hernia	
13	--/--/2015 Ongoing	Current Condition Restless legs syndrome	

#### C4. DIAGNOSIS FOR USE (Continued)

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

#### C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

- 2) AMLODIPINE BESYLATE (AMLODIPINE BESILATE) --/--/2005 to ongoing
- 3) MONTELUKAST (MONTELUKAST) --/--/1990 to ongoing
- 4) ASPIRIN [ACETYLSALICYLIC ACID] (ASPIRIN [ACETYLSALICYLIC ACID]) --/--/2010 to ongoing
- 5) FERROUS SULFATE (FERROUS SULFATE) --/--/1995 to ongoing
- 6) TYLENOL ER (PARACETAMOL) --/--/2018 to ongoing
- 7) COQ10 [UBIDECARENONE] (UBIDECARENONE) --/--/2018 to ongoing
- 8) VITAMIN D3 (COLECALCIFEROL) --/--/2014 to ongoing
- 9) ATORVASTATIN (ATORVASTATIN) --/--/1990 to ongoing
- 10) GABAPENTIN (GABAPENTIN) 07/--/2016 to ongoing
- 11) INDAPAMIDE (INDAPAMIDE) --/--/2019 to ongoing
- 12) LEVOTHYROXINE (LEVOTHYROXINE) --/--/1990 to ongoing
- 13) OMEPRAZOLE (OMEPRAZOLE) --/--/1990 to ongoing
- 14) ROPINIROLE (ROPINIROLE) --/--/2015 to ongoing
- 15) VALSARTAN (VALSARTAN) --/--/2016 to ongoing
- 16) FLOVENT (FLUTICASONE PROPIONATE) --/--/1990 to ongoing

FDA-CBER-2022-1614-4433601

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

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.	08/28/2020 to 08/28/2020	Blinded	Blinded

**MEDWATCH**

3500A Facsimile

For use by user-facilities,  
importers, distributors and manufacturers  
for MANDATORY reporting

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

Page 1 of 3

A. PATIENT INFORMATION			
1. Patient Identifier US3032204	2. Age at Time of Event: 54 Years or Date of Birth: (b) (6)/1966	3. Sex <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight 260.0 lbs or 117.9 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: 11/16/2020 (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) 11/09/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) COVID-19 [COVID-19]			
Case Description: This 54-year-old, White, male subject (US3032204) 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 COVID-19.			
The subject's medical history, as provided by the investigator, included hypercholesterolemia, type I diabetic, C8-9 taken out and replaced with a plate, head contusion due to fall on ice, hypothyroid and headaches. Concomitant medications reported included Armour thyroid, atorvastatin, continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates			
#1 11/11/2020 Blood pressure measurement (continued)			
#2 11/11/2020 Body temperature 37 °C			
#3 11/12/2020 Body temperature 98.6 °F			
#4 11/13/2020 Body temperature 99 °F			
#5 11/14/2020 Body temperature 99 °F			
#6 11/15/2020 Body temperature 99 °F			
continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/1986 to Ongoing Current Condition, (Continued) #2 --/--/2017 to Ongoing Current Condition, (Continued) #3 01/--/2019 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. 08/14/2020 to 08/14/2020	
#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) ARMOUR THYROID (THYROID) 01/--/2019 to ongoing			
2) ARMOUR THYROID (THYROID) 11/--/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 Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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) 11/20/2020	5. (A)NDA # IND # 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 type="checkbox"/> Follow-up #			
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) COVID-19		
E. INITIAL REPORTER			
1. Name and Address Dr. KEITH VRBICKY Meridian Clinical Research Norfolk, NE UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @mcrmed.com	
2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA	
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Physician	<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)

insulin degludec and insulin aspart.

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

On 09 Nov 2020, the subject experienced COVID-19 with a positive SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab collected on 11 Nov 2020. Treatment included oral (PO) acetylsalicylic acid.

From 09 Nov 2020 through 16 Nov 2020, the subject intermittently experienced mild to severe chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches, body aches, headache, nausea, vomiting, and diarrhea. He denied loss of taste, loss of smell, nasal congestion, runny nose, or sore throat.

On 10 Nov 2020, treatment included PO azithromycin, PO methylprednisolone, and PO ondansetron.

On 14 Nov 2020, treatment included respiratory salbutamol.

From 14 Nov 2020 through 16 Nov 2020, the subject's oxygen saturation ranged from 87%-93%.

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

The subject died on 16 Nov 2020. The cause of death was reported as COVID-19. It was unknown if an autopsy was performed.

The investigator assessed the event, COVID-19, as not related to study drug and not related to study procedure.

Follow-up received on 20 Nov 2020 and 24 Nov 2020, included updated COVID-19 symptoms and death date.

### Case Comment/Sender's Comment:

Company Comment: This case concerns a 54-year-old, White, male subject who experienced an unexpected event of COVID-19. The event occurred 2 months 27 days after the first dose of blinded study vaccine administration and 1 month 27 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	11/11/2020	Blood pressure measurement	140/90 mmHg	
7	11/16/2020	Body temperature	97.3 °F	
8	11/11/2020	Heart rate	81 heart beats per minute	
9	11/11/2020	Oxygen saturation	96 percent	
10	11/12/2020	Oxygen saturation	94 percent	
11	11/13/2020	Oxygen saturation	95 percent	
12	11/14/2020	Oxygen saturation	87 percent	
13	11/15/2020	Oxygen saturation	91 percent	
14	11/16/2020	Oxygen saturation	93 percent	
15	11/11/2020	Respiratory rate	16 breaths per minute	
16	11/11/2020	SARS-CoV-2 test Positive		FDA-CBER-2022-1614-4433604

## Nasopharyngeal swab

### B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1986 Ongoing	Current Condition Type 1 diabetes mellitus	
2	--/--/2017 Ongoing	Current Condition Hypothyroidism	
3	01/--/2019 Ongoing	Current Condition Hypercholesterolaemia	
4	01/--/2019 05/--/2019	Historical Condition Headache	
5	03/--/2019 03/--/2019	Historical Condition Contusion	HEAD, DUE TO FALL ON ICE
6	05/--/2019 05/--/2019	Procedure Intervertebral disc operation	C 8-9 TAKEN OUT, REPLACED WITH A PLATE

### C4. DIAGNOSIS FOR USE (Continued)

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

### C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

- 3) ATORVASTATIN (ATORVASTATIN) 01/--/2019 to ongoing
- 4) TRESIBA (INSULIN DEGLUDEC) 03/--/2019 to ongoing
- 5) FIASP FLEXTOUCH (INSULIN ASPART) 06/--/2019 to ongoing

### 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.	09/14/2020 to 09/14/2020	Blinded	Blinded

**MEDWATCH**

3500A Facsimile

For use by user-facilities,  
importers, distributors and manufacturers  
for MANDATORY reporting

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

Page 1 of 4

A. PATIENT INFORMATION			
1. Patient Identifier US3592127	2. Age at Time of Event: 57 Years or Date of Birth: (b) (6)/1963	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 224.7 lbs or 101.9 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"/> 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) 11/11/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) SYMPTOMATIC COVID-19 [COVID-19]			
Case Description: This 57-year-old, White, female subject (US3592127) 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 the non-serious event of symptomatic COVID-19.			
The subject's medical history, as provided by the investigator, included overactive bladder, allergic rhinitis, bilateral knee osteoarthritis, spinal stenosis lumbar, iron deficiency, bilateral carpal tunnel, depression, anxiety, continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 11/13/2020 Blood pressure measurement (continued) #2 11/13/2020 Body temperature 37.1 °C #3 11/14/2020 Body temperature 98 °F #4 11/13/2020 Heart rate (continued) #5 11/13/2020 Oxygen saturation 95 percent #6 11/14/2020 Oxygen saturation 93 percent continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/2005 to Ongoing Current Condition, (Continued) #2 --/--/2008 to Ongoing Current Condition, (Continued) #3 --/--/2008 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. 08/11/2020 to 08/11/2020	
#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) VITAMIN D3 (COLECALCIFEROL) --/--/2008 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 Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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) 11/18/2020	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 type="checkbox"/> Follow-up #		
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) COVID-19		
E. INITIAL REPORTER			
1. Name and Address Dr. Terry Poling Alliance for Multispecialty Research, LLC - East Wichita Wichita, KS UNITED STATES			
Phone # (b) (6)	Email Address (b) (6) @amrlc.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)

hysterectomy, right and left carpal tunnel surgery, idiopathic bilateral feel neuropathy, myopia, hyperopia, hyperlipidemia, sleep apnea, type II diabetes mellitus, acid reflux, irritable bowel syndrome, and menorrhagia. Concomitant medications reported included colecalciferol, acetylsalicylic acid, oxybutynin hydrochloride, probiotics NOS, semaglutide, fluticasone propionate, venlafaxine hydrochloride, celecoxib, multivitamin, ascorbic acid/ boswellia serrata resin/ chondroitin sulfate/ collagen/ glucosamine hydrochloride/ hyaluronic acid/ manganese sulfate/ methylsulfonylmethane/ sodium/ sodium borate, rosuvastatin calcium, and pantoprazole sodium sesquihydrate.

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 11 Aug 2020. The subject's last dose of study drug prior to event onset was on 10 Sep 2020.

On 11 Nov 2020, the subject experienced symptomatic COVID-19. Treatment included oral paracetamol.

From 11 Nov 2020 through 14 Nov 2020, the subject intermittently experienced mild to severe chills, cough, shortness of breath, fatigue, muscle aches, body aches, headache, nasal congestion, runny nose, diarrhea, and sore throat. She denied difficulty breathing, loss of taste, loss of smell, nausea, or vomiting.

On 14 Nov 2020, the subject's oxygen saturation was 93%.

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

The event, symptomatic COVID-19, was reported as not resolved.

The investigator assessed the event, symptomatic COVID-19, as not related to study drug and not related to study procedure.

### Case Comment/Sender's Comment:

This case concerns a 57 year old, White, female subject with medical history of hyperlipidemia and type II diabetes mellitus, who experienced an unexpected event of symptomatic COVID-19. The event occurred 3 months and 1 day after the first dose of the study medication and 2 months and 2 days after the last dose. The event was considered unrelated to the study medication in agreement with the Investigator's assessment.

### B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	11/13/2020	Blood pressure measurement	134/67 mmHg	
4	11/13/2020	Heart rate	58 heart beats per minute	
7	11/13/2020	Respiratory rate	16 breaths per minute	
8	11/13/2020	SARS-CoV-2 test		
		Pending result; Nasopharyngeal swab		

### B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/2005 Ongoing	Current Condition Depression	
2	--/--/2008 Ongoing	Current Condition Hyperlipidaemia	
3	--/--/2008 Ongoing	Current Condition Sleep apnoea syndrome	

4	--/--/2009 Ongoing	Current Condition Myopia	
5	--/--/2009 Ongoing	Current Condition Hypermetropia	
6	--/--/2009 02/--/2019	Historical Condition Menorrhagia	
7	--/--/2010 Ongoing	Current Condition Osteoarthritis	bilateral
8	--/--/2010 Ongoing	Current Condition Gastroesophageal reflux disease	
9	--/--/2012 Ongoing	Current Condition Neuropathy peripheral	feet, idiopathic
10	--/--/2013 Ongoing	Current Condition Type 2 diabetes mellitus	
11	--/--/2015 Ongoing	Current Condition Rhinitis allergic	
12	--/--/2016 06/--/2020	Historical Condition Carpal tunnel syndrome	bilateral
13	--/--/2018 Ongoing	Current Condition Anxiety	
14	12/--/2018 Ongoing	Current Condition Irritable bowel syndrome	
15	02/--/2019 Ongoing	Current Condition Iron deficiency	
16	02/--/2019 02/--/2019	Procedure Hysterectomy	
17	05/--/2019 Ongoing	Current Condition Hypertonic bladder	
18	08/--/2019 08/--/2019	Procedure Carpal tunnel decompression	right
19	04/--/2020 Ongoing	Current Condition Lumbar spinal stenosis	
20	06/--/2020 06/--/2020	Procedure Carpal tunnel decompression	left

## C4. DIAGNOSIS FOR USE (Continued)

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

## C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

2) ASPIRIN [ACETYLSALICYLIC ACID] (ASPIRIN [ACETYLSALICYLIC ACID]) --/--/2010 to ongoing

3) OXYBUTYNINE HCL (OXYBUTYNIN HYDROCHLORIDE) 06/--/2019 to ongoing

4) PROBIOTICS NOS (PROBIOTICS NOS) --/--/2018 to ongoing

5) OZEMPIC (SEMAGLUTIDE) 02/--/2019 to ongoing

6) FLONASE ALLERGY RELIEF (FLUTICASONE PROPIONATE) --/--/2015 to ongoing

7) EFFEXOR (VENLAFAXINE HYDROCHLORIDE) --/--/2015 to ongoing

8) CELEBREX (CELECOXIB) --/--/2018 to ongoing

9) MULTIVITAMIN [VITAMINS NOS] (MULTIVITAMIN [VITAMINS NOS]) 08/--/2019 to ongoing

10) OSTEO BI-FLEX [ASCORBIC ACID;BOSWELLIA SERRATA RESIN;CHONDROITIN SULFATE;COLLAGEN;GLUCOSAMINE HYDROCHLORIDE;HYALURONIC ACID;MANGANESE SULFATE;METHYLSULFONYLMETHANE;SODIUM;SODIUM BORATE] (ASCORBIC ACID, BOSWELLIA SERRATA RESIN, CHONDROITIN SULFATE, COLLAGEN, GLUCOSAMINE HYDROCHLORIDE, HYALURONIC ACID, MANGANESE SULFATE, METHYLSULFONYLMETHANE, SODIUM, SODIUM BORATE) 01/--/2020 to ongoing

11) CRESTOR (ROSUVASTATIN CALCIUM) --/--/2010 to ongoing

12) PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] (PANTOPRAZOLE SODIUM SESQUIHYDRATE) --/--/2010 to ongoing

## 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.	09/10/2020 to 09/10/2020	Blinded	Blinded

**MEDWATCH**

3500A Facsimile

For use by user-facilities,  
importers, distributors and manufacturers  
for MANDATORY reporting

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

Page 1 of 3

A. PATIENT INFORMATION			
1. Patient Identifier US3412259	2. Age at Time of Event: 67 Years or Date of Birth: (b) (6)/1953	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 153.2 lbs or 69.5 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"/> 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) 11/03/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) SYMPTOMATIC COVID-19 [COVID-19]  Case Description: This 67-year-old, White, female subject (US3412259) 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 the non-serious event of symptomatic COVID-19.  The subject's medical history, as provided by the investigator, included migraine headache, right shoulder osteoarthritis, ovarian cancer history, and hysterectomy. Concomitant medications reported included sumatriptan continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 11/09/2020 Blood pressure measurement (continued) #2 11/09/2020 Body temperature (continued) #3 11/10/2020 Body temperature 97.2 °F #4 11/11/2020 Body temperature 96.4 °F #5 11/12/2020 Body temperature 97.1 °F #6 11/13/2020 Body temperature 99.1 °F continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/1963 to Ongoing, Current Condition, Migraine #2 --/--/2002 to --/--/2003, Historical Condition, Ovarian cancer #3 --/--/2003 to --/--/2003, Procedure, Hysterectomy #4 --/--/2015 to Ongoing, Current Condition, Osteoarthritis (RIGHT)			

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. 08/17/2020 to 08/17/2020	
#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) IMITREX DF (SUMATRIPTAN SUCCINATE) --/--/2010 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 Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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 type="checkbox"/> Follow-up #		
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) COVID-19		
E. INITIAL REPORTER			
1. Name and Address Dr. GREGORY GOTTSCHLICH New Horizons Clinical Research 4260 GLENDALE MILFORD ROAD CINCINNATI, Ohio 45242 UNITED STATES			
Phone # (b) (6)	Email Address (b) (6) @velocityclinical.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)

succinate, celecoxib, and influenza vaccine.

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 17 Aug 2020. The subject's last dose of study drug prior to event onset was on 21 Sep 2020.

On 03 Nov 2020, the subject experienced symptomatic COVID-19 with a positive rapid COVID-19 test from her employer on 06 Nov 2020 and a positive SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab collected on 09 Nov 2020.

From 03 Nov 2020 through 16 Nov 2020, the subject intermittently experienced mild to moderate cough, fatigue, muscle aches, body aches, headache, nasal congestion, runny nose, and sore throat. She denied chills, shortness of breath, difficulty breathing, loss of taste, loss of smell, nausea, vomiting, or diarrhea.

On 08 Nov 2020, treatment included oral pseudoephedrine hydrochloride.

On 11 Nov 2020 and 12 Nov 2020, the subject's oxygen saturation was 93% and 91%, respectively.

On 13 Nov 2020, oxygen saturation returned to normal, 99%.

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

The event, symptomatic COVID-19, was reported as resolving.

The investigator assessed the event, symptomatic COVID-19, as not related to study drug and not related to study procedure.

### Case Comment/Sender's Comment:

Company Comment: This case concerns a 67-year-old, White, female subject with medical history of ovarian cancer, who experienced an unexpected event of symptomatic COVID-19.. The event occurred 2 months 18 days after the first dose of blinded study vaccine administration and 1 month 14 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	11/09/2020	Blood pressure measurement	128/89 mmHg	
2	11/09/2020	Body temperature	36.8 degree Celsius	
7	11/14/2020	Body temperature	96.3 °F	
8	11/15/2020	Body temperature	97.0 °F	
9	11/16/2020	Body temperature	97.1 °F	
10	11/17/2020	Body temperature	97.4 °F	
11	11/09/2020	Heart rate	88 heart beats per minute	
12	11/10/2020	Oxygen saturation	99 percent	
13	11/11/2020	Oxygen saturation	93 percent	
14	11/12/2020	Oxygen saturation	91 percent	
15	11/13/2020	Oxygen saturation	99 percent	FDA-CBER-2022-1614-4433611



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

16	11/14/2020	Oxygen saturation	98 percent
17	11/15/2020	Oxygen saturation	99 percent
18	11/16/2020	Oxygen saturation	98 percent
19	11/17/2020	Oxygen saturation	95 percent
20	11/09/2020	Respiratory rate	18 breaths per minute
21	11/09/2020	SARS-CoV-2 test Positive Nasopharyngeal Swab	

#### C4. DIAGNOSIS FOR USE (Continued)

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

#### C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

2) CELEBREX (CELECOXIB) 01/12/2020 to ongoing

3) INFLUENZA VACCINE (INFLUENZA VACCINE) 10/08/2020 to 10/08/2020

#### 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.	09/21/2020 to 09/21/2020	Blinded	Blinded

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

<b>A. PATIENT INFORMATION</b>			
1. Patient Identifier US3272196	2. Age at Time of Event: 59 Years or Date of Birth: (b) (6)/1961	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 244.3 lbs or 110.8 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 type="checkbox"/> Death: (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) 11/05/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) COVID 19 [COVID-19]			
Case Description: This 59-year-old, White, female subject (US3272196) 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 the non-serious event of COVID 19.			
The subject's medical history, as provided by the investigator, included hypertension, bilateral knee replacement, endometrial ablation, severe obesity, menopause and postmenopause. No relevant concomitant medications were reported. continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 11/09/2020 Blood pressure measurement (continued) #2 11/09/2020 Body temperature (continued) #3 11/10/2020 Body temperature 99.8 °F #4 11/11/2020 Body temperature 100.9 °F #5 11/12/2020 Body temperature 100.3 °F #6 11/13/2020 Body temperature 101.5 °F continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/2008 to --/--/2013, Historical Condition, Hypertension #2 --/--/2011 to --/--/2012, Historical Condition, Menopause #3 --/--/2012 to --/--/2016, Procedure, Endometrial ablation continued in additional info section...			

<b>C. SUSPECT PRODUCT(S)</b>			
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. 08/19/2020 to 08/19/2020	
#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)			
<b>G. ALL MANUFACTURERS</b>			
1. Contact Office (and Manufacturing Site for Devices)		2. Phone Number	
Name ModernaTX, Inc. David Martin Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<input type="checkbox"/> Foreign	
4. Date Received by Manufacturer (mm/dd/yyyy) 11/19/2020		<input checked="" type="checkbox"/> Study	
6. If IND, Give Protocol # mRNA-1273-P301		<input type="checkbox"/> Literature	
7. Type of Report (Check all that apply)		<input type="checkbox"/> Consumer	
<input type="checkbox"/> 5-day <input type="checkbox"/> 30-day		<input checked="" type="checkbox"/> Health Professional	
<input type="checkbox"/> 7-day <input type="checkbox"/> Periodic		<input type="checkbox"/> User Facility	
<input type="checkbox"/> 10-day <input type="checkbox"/> Initial		<input type="checkbox"/> Company Representative	
<input type="checkbox"/> 15-day <input type="checkbox"/> Follow-up #		<input type="checkbox"/> Distributor	
Combination Product <input type="checkbox"/> Yes		<input type="checkbox"/> Other:	
Pre-1938 <input type="checkbox"/> Yes			
OTC Product <input type="checkbox"/> Yes			
9. Manufacturer Report Number (b) (6)		8. Adverse Event Term(s) COVID-19	
<b>E. INITIAL REPORTER</b>			
1. Name and Address Dr. Adam Brosz Grand Island, NE 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)

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 19 Aug 2020. The subject's last dose of study drug prior to event onset was on 16 Sep 2020.

On 05 Nov 2020, the subject experienced COVID 19, which was confirmed by positive SARS-CoV-2 real time reverse transcriptase polymerase chain reaction testing via nasopharyngeal swab on 09 Nov 2020. No treatment information was reported by the investigator.

From 05 Nov 2020 to 18 Nov 2020, the subject intermittently experienced mild to moderate symptoms of chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, new loss of taste, new loss of smell, nasal congestion, runny nose (rhinorrhea), nausea, vomiting and diarrhea. She denied having a sore throat.

On 09 Nov 2020, vital signs included oxygen saturation 97%, temperature 36.5 degrees Celsius, pulse 64 beats/min, respirations 18 breaths/min and blood pressure 139/89 mmHg.

On 10 Nov 2020, oxygen saturation was 92%.

On 11 Nov 2020, oxygen saturation was 93% and temperature was 100.9 degrees Fahrenheit (F).

On 13 Nov 2020, oxygen saturation was 93% and temperature was 101.5 degrees F.

On 14 Nov 2020, oxygen saturation was 93% and temperature was 98.7 degrees F.

On 15 Nov 2020, oxygen saturation was 93%.

On 16 Nov 2020, oxygen saturation was 92%.

On 17 Nov 2020, oxygen saturation was 96%.

On 19 Nov 2020, symptoms resolved.

Action taken with the study drug dosing was not applicable as the subject had already received both scheduled doses.

The event, COVID 19, was considered resolved on 19 Nov 2020.

The investigator assessed the event, COVID 19, as not related to study drug and not related to study procedure.

#### Case Comment/Sender's Comment:

Company Comment: This case concerns a 59-year-old, White, female subject with medical history of hypertension and severe obesity, who experienced an unexpected event of COVID 19. The event occurred 2 months 18 days after the first study vaccine administration and 1 month 21 days after the last study vaccine 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	11/09/2020	Blood pressure measurement	139/89 mmHg	
2	11/09/2020	Body temperature	36.5 °C	
		Temporal		
7	11/14/2020	Body temperature	98.7 °F	
8	11/15/2020	Body temperature	98.6 °F	
9	11/16/2020	Body temperature	97.8 °F	FDA-CBER-2022-1614-4433614

10	11/17/2020	Body temperature	97.3 °F
11	11/18/2020	Body temperature	97.4 °F
12	11/19/2020	Body temperature	96.6 °F
13	11/09/2020	Heart rate	64 heart beats per minute
14	11/09/2020	Oxygen saturation	97 percent
15	11/10/2020	Oxygen saturation	92 percent
16	11/11/2020	Oxygen saturation	93 percent
17	11/12/2020	Oxygen saturation	94 percent
18	11/13/2020	Oxygen saturation	93 percent
19	11/14/2020	Oxygen saturation	93 percent
20	11/15/2020	Oxygen saturation	93 percent
21	11/16/2020	Oxygen saturation	92 percent
22	11/17/2020	Oxygen saturation	96 percent
23	11/18/2020	Oxygen saturation	96 percent
24	11/19/2020	Oxygen saturation	97 percent
25	11/09/2020	Respiratory rate	18 breaths per minute
26	11/09/2020	SARS-CoV-2 test Positive Nasopharyngeal swab	

## B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
4	--/--/2012 Ongoing	Current Condition Postmenopause	
5	--/--/2014 Ongoing	Current Condition Obesity	Severe
6	--/--/2016 --/--/2016	Procedure Knee arthroplasty	Bilateral

## C4. DIAGNOSIS FOR USE (Continued)

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

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

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.	09/16/2020 to 09/16/2020	Blinded	Blinded

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

<b>A. PATIENT INFORMATION</b>			
1. Patient Identifier US3142255	2. Age at Time of Event: 23 Years or Date of Birth: (b) (6)/1996	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 type="checkbox"/> Death: _____ (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) 11/13/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) COVID-19 [COVID-19]  Case Description: This 23 year old, White, male subject (US3142255) 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 the non-serious event of COVID-19.  The subject's medical history, as provided by the investigator, included bilateral astigmatism, intermittent back pain, hepatitis C, lactose intolerance, and matte tea sensitivity.  continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 11/16/2020 Blood pressure measurement (continued) #2 11/16/2020 Body temperature 98.2 °F #3 11/17/2020 Body temperature 99.0 °F #4 11/18/2020 Body temperature 99.4 °F #5 11/19/2020 Body temperature 99.6 °F #6 11/16/2020 Heart rate (continued) continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/2018 to Ongoing, Current Condition, Astigmatism #2 --/--/2018 to 02/--/2020, Historical Condition, Hepatitis C #3 --/--/2018 to Ongoing, Current Condition, Lactose intolerance continued in additional info section...			

<b>C. SUSPECT PRODUCT(S)</b>			
1. Name (Give labeled strength & mfr/labeler) (Regimens Continued) #1. mRNA-1273 vs Placebo (Code not broken) #2.			
2. Dose, Frequency & Route Used #1. Blinded, Information withheld. #2.		3. Therapy Dates (if unknown, give duration) from/to (or best estimate) #1. 08/26/2020 to 08/26/2020 #2.	
4. Diagnosis for Use (Indication) #1. COVID-19 (Continued) #2.		5. Event Abated After Use Stopped or Dose Reduced? #1. <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't Apply #2. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
6. Lot # #1. Blinded #2.	7. Exp. Date #1. Blinded #2.	8. Event Reappeared After Reintroduction? #1. <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't Apply #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)			
<b>G. ALL MANUFACTURERS</b>			
1. Contact Office (and Manufacturing Site for Devices) Name ModernaTX, Inc. David Martin Dr. Address 200 Technology Square Cambridge, MA 02139 UNITED STATES Email Address drugsafety@modernatx.com		2. Phone Number 617-335-1804	
4. Date Received by Manufacturer (mm/dd/yyyy) 11/20/2020		3. Report Source (Check all that apply) <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: _____	
6. If IND, Give Protocol # mRNA-1273-P301		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	
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 type="checkbox"/> Follow-up # _____		8. Adverse Event Term(s) COVID-19	
9. Manufacturer Report Number (b) (6)		8. Adverse Event Term(s) COVID-19	
<b>E. INITIAL REPORTER</b>			
1. Name and Address Dr. RIPLEY HOLLISTER Lynn Institute of The Rockies COLORADO SPRINGS, Colorado UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @lhsi.net	
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)

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 26 Aug 2020. The subject's last dose of study drug prior to event onset was on 23 Sep 2020.

On 13 Nov 2020, the subject experienced COVID-19, with a positive for SARS-CoV-2 by reverse transcriptase polymerase chain reaction via nasopharyngeal swab on 16 Nov 2020.

From 13 Nov 2020 through 19 Nov 2020, the subject experienced mild to severe symptoms of shortness of breath, difficulty breathing, muscle aches, body aches, headache, new loss of smell and taste, nasal congestion, fatigue and runny nose. The subject denied symptoms of chills, cough, nausea, vomiting, diarrhea and sore throat.

On 16 Nov 2020, vital signs included oxygen saturation 98%, temperature temporal 98.2 degrees Fahrenheit, pulse 76 beats/min, respiratory rate 14 breaths/min and blood pressure 107/59 mmHg.

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

The event, COVID-19, was considered not resolved.

The investigator assessed the event, COVID-19, as?not related to study drug or study procedure.

### Case Comment/Sender's Comment:

This case concerns a 23-year-old male subject who experienced the unlisted event of COVID-19. The event occurred 2 months 19 days after the first dose of IP and 1 month 22 days after the second dose of IP. The event was considered unrelated to IP in agreement with the Investigator.

### B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	11/16/2020	Blood pressure measurement	107/59 mmHg	
6	11/16/2020	Heart rate	76 heart beats per minute	
7	11/16/2020	Oxygen saturation	98 percent	
8	11/17/2020	Oxygen saturation	97 percent	
9	11/18/2020	Oxygen saturation	95 percent	
10	11/19/2020	Oxygen saturation	96 percent	
11	11/16/2020	Respiratory rate	14 breaths per minute	
12	11/16/2020	SARS-CoV-2 test Positive Nasopharyngeal swab		

### B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
4	--/--/2018 Ongoing	Current Condition Food allergy	
5	06/--/2019 Ongoing	Current Condition Back pain	

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

C4. DIAGNOSIS FOR USE (Continued)  
#1:COVID-19 vaccination (COVID-19 immunisation)

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.	09/23/2020 to 09/23/2020	Blinded	Blinded



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

A. PATIENT INFORMATION			
1. Patient Identifier US3272357	2. Age at Time of Event: 41 Years or Date of Birth: (b) (6)/1979	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 148.0 lbs or 67.1 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"/> 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) 11/09/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) COVID 19 [COVID-19]  Case Description: This 41 year old, Hispanic or Latino, female subject (US3272357) 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 the non-serious event of COVID 19.  The subject's medical history, as provided by the investigator, included herpes simplex virus 1 (lips/mouth), diabetes mellitus type 1 and left foot bunion. Concomitant medications reported included empagliflozin, insulin lispro, valaciclovir hydrochloride, etonogestrel, influenza vaccine and continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 11/10/2020 Blood pressure measurement (continued) #2 11/10/2020 Body temperature 99.0 °F #3 11/11/2020 Body temperature 100.1 °F #4 11/12/2020 Body temperature 99.3 °F #5 11/13/2020 Body temperature 100.1 °F #6 11/14/2020 Body temperature 100.4 °F continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) #1 --/--/2009 to Ongoing, Current Condition, Type 1 diabetes mellitus #2 --/--/2017 to Ongoing, Current Condition, Herpes simplex (Virus lips/mouth) #3 --/--/2018 to Ongoing, Current Condition, Foot deformity (Left foot)			

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event

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. 08/25/2020 to 08/25/2020	
#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) EMPAGLIFLOZIN (EMPAGLIFLOZIN) --/--/2012 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 Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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 # 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 type="checkbox"/> Follow-up #			
9. Manufacturer Report Number (b) (6)		8. Adverse Event Term(s) COVID-19	
E. INITIAL REPORTER			
1. Name and Address Dr. ADAM BROSZ Meridian Clinical Research (Grand Island, Nebraska) 2444 W. FAIDLEY AVE GRAND ISLAND, NE 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	

## ADDITIONAL INFORMATION

### B5. EVENT DESCRIPTION (Continued)

acetylsalicylic acid.

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 25 Aug 2020. The subject's last dose of study drug prior to event onset was on 22 Sep 2020.

On 09 Nov 2020, the subject experienced COVID 19 with a positive SARS-CoV-2 by real time reverse transcription polymerase chain reaction nasopharyngeal swab collected on 10 Nov 2020. The subject reported she had been exposed to son's friend.

From 09 Nov 2020 to 02 Dec 2020 the subject intermittently experienced mild to severe symptoms of cough, shortness of breath, fatigue, muscle aches, body aches, headache, sore throat, runny nose, nasal congestion, chills, loss of taste, loss of smell, nausea and difficulty breathing. Subject denied symptoms of vomiting and diarrhea.

On 10 Nov 2020, vital signs included oxygen saturation 99%, temperature 99 degrees Fahrenheit, pulse 94 beats/min, respiratory rate 16 breaths/min and blood pressure 124/58 mmHg.

On 14 Nov 2020 the subject's temperature was 100.4 degrees Fahrenheit.

On 15 Nov 2020, temperature was 101.5 degrees Fahrenheit.

On 17 Nov 2020, oxygen saturation was 89% and temperature 101.9 degrees Fahrenheit.

On 18 Nov 2020, oxygen saturation was 95% and temperature 98.1 degrees Fahrenheit and remained normal. No treatment was administered for the event.

Action taken with study drug was reported as not applicable in response to the event, as the subject had already received both scheduled doses.

The event, COVID 19, was considered resolving.

The investigator assessed the event, COVID 19, as not related to study drug and not related to study procedure.

Follow-up received on 01 Dec 2020 included an updated symptom log.

### Case Comment/Sender's Comment:

This case concerns a 41-year-old female subject who experienced an unexpected event of COVID-19. The event occurred 11 month 19 days after the second dose of blinded study medication administration. The event was considered unrelated to the blinded study medication in agreement with the Investigator. Subject was exposed to son's friend diagnosed with COVID-19.

### B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	11/10/2020	Blood pressure measurement	124/58 mmHg	
7	11/15/2020	Body temperature	101.5 °F	
8	11/16/2020	Body temperature	99.8 °F	
9	11/17/2020	Body temperature	101.9 °F	
10	11/18/2020	Body temperature	98.1 °F	
11	11/19/2020	Body temperature	99.1 °F	
12	11/20/2020	Body temperature	98.3 °F	
13	11/21/2020	Body temperature	99.1 °F	FDA-CBER-2022-1614-4433621

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

14	11/22/2020	Body temperature	99.3 °F
15	11/23/2020	Body temperature	99.1 °F
16	11/24/2020	Body temperature	98.2 °F
17	11/25/2020	Body temperature	98.1 °F
18	11/26/2020	Body temperature	98.3 °F
19	11/27/2020	Body temperature	99.1 °F
20	11/28/2020	Body temperature	99.3 °F
21	11/29/2020	Body temperature	98.9 °F
22	11/30/2020	Body temperature	98.6 °F
23	12/01/2020	Body temperature	99.1 °F
24	12/02/2020	Body temperature	98.6 °F
25	11/10/2020	Heart rate	94 heart beats per minute
26	11/10/2020	Oxygen saturation	99 percent
27	11/11/2020	Oxygen saturation	100 percent
28	11/12/2020	Oxygen saturation	99 percent
29	11/13/2020	Oxygen saturation	99 percent
30	11/14/2020	Oxygen saturation	97 percent
31	11/15/2020	Oxygen saturation	94 percent
32	11/16/2020	Oxygen saturation	99 percent
33	11/17/2020	Oxygen saturation	89 percent
34	11/18/2020	Oxygen saturation	95 percent
35	11/19/2020	Oxygen saturation	96 percent
36	11/20/2020	Oxygen saturation	96 percent
37	11/21/2020	Oxygen saturation	99 percent
38	11/22/2020	Oxygen saturation	99 percent
39	11/23/2020	Oxygen saturation	99 percent
40	11/24/2020	Oxygen saturation	99 percent

FDA-CBER-2022-1614-4433622

41	11/25/2020	Oxygen saturation	99 percent
42	11/26/2020	Oxygen saturation	99 percent
43	11/27/2020	Oxygen saturation	96 percent
44	11/28/2020	Oxygen saturation	96 percent
45	11/29/2020	Oxygen saturation	99 percent
46	11/30/2020	Oxygen saturation	99 percent
47	12/01/2020	Oxygen saturation	99 percent
48	12/02/2020	Oxygen saturation	99 percent
49	11/10/2020	Respiratory rate	16 breaths per minute
50	11/10/2020	SARS-CoV-2 test Positive Nasopharyngeal Swab	OTHER

#### C4. DIAGNOSIS FOR USE (Continued)

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

#### C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

- 2) HUMALOG (INSULIN LISPRO) 01/--/2020 to ongoing
- 3) VALACYCLOVIR HCL (VALACICLOVIR HYDROCHLORIDE) --/--/2017 to ongoing
- 4) NEXPLANON (ETONOGESTREL) --/--/2019 to ongoing
- 5) INFLUENZA VACCINE (INFLUENZA VACCINE) 10/17/2020 to 10/17/2020
- 6) ASPIRIN (E.C.) (ACETYLSALICYLIC ACID) 10/23/2020 to ongoing

#### 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.	09/22/2020 to 09/22/2020	Blinded	Blinded

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

A. PATIENT INFORMATION			
1. Patient Identifier US3142252	2. Age at Time of Event: 58 Years or Date of Birth: (b) (6)/1962	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 type="checkbox"/> Death: _____ (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) 11/07/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) COVID-19 INFECTION [COVID-19]			
Case Description: This 58-year-old, White, female subject (US3142252) 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 the non-serious event of COVID-19 infection.			
The subject's medical history, as provided by the investigator, included bilateral nearsighted, bilateral ringing in ears, postnasal drip, seasonal allergies, intermittent mouth sores, hypothyroidism, and menopause. Concomitant medications reported included levothyroxine sodium. continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates			
#1 11/11/2020 Body temperature 97.1 °F			
#2 11/12/2020 Body temperature 97.7 °F			
#3 11/13/2020 Body temperature 97.9 °F			
#4 11/14/2020 Body temperature 98.0 °F			
#5 11/15/2020 Body temperature 97.8 °F			
#6 11/16/2020 Body temperature 98.0 °F			
continued in additional info section...			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: White #1 --/--/1972 to Ongoing Current Condition, (Continued) #2 --/--/1974 to Ongoing Current Condition, (Continued) #3 --/--/1984 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. 08/25/2020 to 08/25/2020	
#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) SYNTHROID (LEVOTHYROXINE SODIUM) --/--/1984 to ongoing			
G. ALL MANUFACTURERS			
1. Contact Office (and Manufacturing Site for Devices)		2. Phone Number	
Name ModernaTX, Inc. David Martin Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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) 11/20/2020	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 type="checkbox"/> Follow-up # _____			
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) COVID-19		
E. INITIAL REPORTER			
1. Name and Address continued in additional info section Dr. RIPLEY HOLLISTER Lynn Institute of The Rockies 4190 EAST WOODMEN ROAD SUITE 210 COLORADO SPRINGS, Colorado 80920 UNITED			
Phone # (b) (6)	Email Address (b) (6) @lhsi.net		
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)

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 25 Aug 2020. The subject's last dose of study drug prior to event onset was on 22 Sep 2020.

On 07 Nov 2020, the subject experienced COVID-19 infection with a positive COVID-19 test (not at site) collected on 09 Nov 2020 and a positive SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab collected on 11 Nov 2020.

From 07 Nov 2020 through 19 Nov 2020, the subject intermittently experienced mild to severe chills, cough, fatigue, muscle aches, body aches, headache, loss of taste, loss of smell, nasal congestion, nausea, and diarrhea. She denied shortness of breath, difficulty breathing, runny nose, vomiting, or sore throat. The subject's oxygen saturation ranged intermittently from 90% to 97%.

On 11 Nov 2020, treatment included oral azithromycin and oral hydroxychloroquine.

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

The event, COVID-19 infection, was reported as not resolved.

The investigator assessed the event, COVID-19 infection, as not related to study drug and not related to study procedure.

#### Case Comment/Sender's Comment:

This case concerns a 58-year-old female subject who experienced an unexpected event of COVID-19 infection. The event occurred 1 month 17 days after the second dose of blinded study vaccine administration. The event was considered unrelated to the blinded study medication in agreement with the Investigator.

### B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
7	11/17/2020	Body temperature	98.0 °F	
8	11/18/2020	Body temperature	97.7 °F	
9	11/19/2020	Body temperature	97.7 °F	
10	11/11/2020	Oxygen saturation	90 percent	
11	11/12/2020	Oxygen saturation	94 percent	
12	11/13/2020	Oxygen saturation	93 percent	
13	11/14/2020	Oxygen saturation	96 percent	
14	11/15/2020	Oxygen saturation	95 percent	
15	11/16/2020	Oxygen saturation	94 percent	
16	11/17/2020	Oxygen saturation	97 percent	
17	11/18/2020	Oxygen saturation	93 percent	
18	11/19/2020	Oxygen saturation	93 percent	
19	11/09/2020	SARS-CoV-2 test Positive		
20	11/11/2020	SARS-CoV-2 test Positive		FDA-CBER-2022-1614-4433625

## Nasopharyngeal swab

### B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1972 Ongoing	Current Condition Stomatitis	INTERMITTENT
2	--/--/1974 Ongoing	Current Condition Myopia	Bilateral
3	--/--/1984 Ongoing	Current Condition Hypothyroidism	
4	--/--/1985 Ongoing	Current Condition Upper-airway cough syndrome	
5	--/--/2015 Ongoing	Current Condition Menopause	
6	01/--/2020 Ongoing	Current Condition Tinnitus	Bilateral
7	01/--/2020 Ongoing	Current Condition Seasonal allergy	

### C4. DIAGNOSIS FOR USE (Continued)

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

### E1. NAME AND ADDRESS (Continued)

Dr. RIPLEY HOLLISTER

Lynn Institute of The Rockies

4190 EAST WOODMEN ROAD SUITE 210 COLORADO SPRINGS, Colorado 80920 UNITED STATES

### 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.	09/22/2020 to 09/22/2020	Blinded	Blinded



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

A. PATIENT INFORMATION			
1. Patient Identifier US3452203	2. Age at Time of Event: 80 Years or Date of Birth: (b) (6)/1940	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 198.0 lbs or 89.8 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"/> 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) 11/17/2020		4. Date of This Report (mm/dd/yyyy) 12/05/2020	
5. Describe Event or Problem Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) COVID 19 [COVID-19]  Case Description: This 80-years-old, White, female subject (US3452203) 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 the non-serious event, COVID 19.  The subject's medical history, as provided by the investigator, included cholecystectomy, glaucoma, left knee replacement surgery, right knee replacement, bowl resection, bunions removed from both feet, rotator cuff repair of right shoulder, nasal reconstruction due to injury, allergy to sulfa, continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 11/17/2020 Blood pressure measurement (continued) #2 11/17/2020 Body temperature 98.0 °F #3 11/18/2020 Body temperature 98.9 °F #4 11/19/2020 Body temperature 98.2 °F #5 11/20/2020 Body temperature 99.0 °F #6 11/21/2020 Body temperature 97.7 °F continued in additional info section...			
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 Current Condition, (Continued) #2 --/--/1976 to Ongoing Allergy, (Continued) #3 --/--/1985 to Ongoing Allergy, (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. 08/04/2020 to 08/04/2020	
#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) EZETIMIBE (EZETIMIBE) --/--/2015 to ongoing 2) ARMOUR THYROID (THYROID) --/--/2016 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 Dr.		617-335-1804	
Address 200 Technology Square Cambridge, MA 02139 UNITED STATES		3. Report Source (Check all that apply)	
Email Address drugsafety@modernatx.com		<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) 11/23/2020	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 type="checkbox"/> Follow-up #			
9. Manufacturer Report Number (b) (6)	8. Adverse Event Term(s) COVID-19		
E. INITIAL REPORTER			
1. Name and Address Dr. Carl Griffin Lynn Health Science Institute Oklahoma City, Oklahoma UNITED STATES			
Phone # (b) (6)		Email Address (b) (6) @lhsi.net	
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)

allergy to codeine and morphine, allergy to Nar-Can, gallstones, seasonal allergies, dysmenorrhea, non-cancerous growth in bowel, high blood pressure, gastroesophageal reflux disease, hypocholesterolemia, hypothyroidism, sensory neuropathy of bilateral extremities, restless leg syndrome, osteoarthritis of all joints, and complete hysterectomy. Concomitant medications reported included ezetimibe, thyroid, turmeric, diclofenac sodium, levothyroxine, spironolactone, pantoprazole, diclofenac, ropinirole, tramadol, gabapentin, and oxymetazoline hydrochloride.

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 04 Aug 2020. The subject's last dose of study drug prior to event onset was on 03 Sep 2020.

On 17 Nov 2020, the subject experienced COVID 19 with a positive SARS-CoV-2 real-time reverse transcription polymerase chain reaction nasopharyngeal swab.

From 17 Nov 2020 to 30 Nov 2020, the subject intermittently experienced symptoms including mild cough, shortness of breath, difficulty breathing, runny nose, and diarrhea. The subject denied experiencing chills fatigue, myalgia, body aches, headache, new loss of smell or taste, nasal congestion, nausea, vomiting, or sore throat.

On 17 Nov 2020, the subject's vital signs included temperature 98.0 degrees F, pulse 86 beats/min, respiratory rate 20 breaths/min, and blood pressure 130/65 mmHg.

On 17 Nov 2020, the subject's vital signs included oxygen saturation 93%.

On 18 Nov 2020, the subject's vital signs included oxygen saturation 92%.

On 19 Nov 2020, the subject's vital signs included oxygen saturation 91%.

On 21 Nov 2020, the subject's vital signs included oxygen saturation 93%.

No treatment information was reported by the investigator.

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

The event, COVID 19, was reported as not resolved.

The investigator assessed the event, COVID 19, as not related to study drug and not related to study procedure.

### B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	11/17/2020	Blood pressure measurement	130/65 mmHg	
7	11/22/2020	Body temperature	97.8 °F	
8	11/23/2020	Body temperature	98.3 °F	
9	11/24/2020	Body temperature	98.4 °F	
10	11/25/2020	Body temperature	97.7 °F	
11	11/26/2020	Body temperature	97.4 °F	
12	11/27/2020	Body temperature	97.9 °F	
13	11/28/2020	Body temperature	97.4 °F	
14	11/29/2020	Body temperature	97.7 °F	

FDA-CBER-2022-1614-4433628

15	11/30/2020	Body temperature	97.4 °F
16	11/17/2020	Heart rate	86 heart beats per minute
17	11/17/2020	Oxygen saturation	93 percent
18	11/18/2020	Oxygen saturation	92 percent
19	11/19/2020	Oxygen saturation	91 percent
20	11/20/2020	Oxygen saturation	91 percent
21	11/21/2020	Oxygen saturation	93 percent
22	11/22/2020	Oxygen saturation	93 percent
23	11/23/2020	Oxygen saturation	93 percent
24	11/24/2020	Oxygen saturation	93 percent
25	11/25/2020	Oxygen saturation	93 percent
26	11/26/2020	Oxygen saturation	93 percent
27	11/27/2020	Oxygen saturation	93 percent
28	11/28/2020	Oxygen saturation	93 percent
29	11/29/2020	Oxygen saturation	93 percent
30	11/30/2020	Oxygen saturation	93 percent
31	11/17/2020	Respiratory rate	20 breaths per minute
32	11/17/2020	SARS-CoV-2 test Positive Nasopharyngeal Swab	

## B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	--/--/1970 Ongoing	Current Condition Hypothyroidism	
2	--/--/1976 Ongoing	Allergy Drug hypersensitivity	Sulfa
3	--/--/1985 Ongoing	Allergy Drug hypersensitivity	Codeine

4	--/--/1985 Ongoing	Allergy Drug hypersensitivity	Nar-Can
5	--/--/1985 --/--/1985	Historical Condition Dysmenorrhoea	
6	--/--/1985 --/--/1985	Procedure Hysterectomy	Complete
7	--/--/1985 Ongoing	Allergy Drug hypersensitivity	Morphine
8	--/--/1994 --/--/1994	Procedure Cholecystectomy	
9	--/--/1994 --/--/1994	Historical Condition Cholelithiasis	
10	--/--/2001 --/--/2001	Procedure Intestinal resection	
11	--/--/2001 --/--/2001	Historical Condition Benign neoplasm	Bowel
12	--/--/2003 --/--/2003	Procedure Bunion operation	Both feet
13	--/--/2005 --/--/2005	Procedure Knee arthroplasty	Left
14	--/--/2007 --/--/2007	Procedure Knee arthroplasty	Right
15	--/--/2009 --/--/2009	Procedure Rotator cuff repair	
16	--/--/2010 --/--/2010	Procedure Nasal operation	Reconstruction due to injury
17	--/--/2012 --/--/2012	Historical Condition Glaucoma	
18	--/--/2015 Ongoing	Current Condition Seasonal allergy	
19	--/--/2015 Ongoing	Current Condition Hypocholesterolaemia	
20	--/--/2015 Ongoing	Current Condition Restless legs syndrome	

21	--/--/2016 Ongoing	Current Condition Hypertension	
22	--/--/2016 Ongoing	Current Condition Gastroesophageal reflux disease	
23	--/--/2017 Ongoing	Current Condition Peripheral sensory neuropathy	Bilateral extremities
24	--/--/2018 Ongoing	Current Condition Osteoarthritis	All joints

## C4. DIAGNOSIS FOR USE (Continued)

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

## C10. CONCOMITANT MEDICAL PRODUCTS (Continued)

- 3) TURMERIC [CURCUMA LONGA RHIZOME] (TURMERIC [CURCUMA LONGA RHIZOME]) 04/--/2020 to ongoing
- 4) DICLOFENAC SODIUM (DICLOFENAC SODIUM) 04/--/2020 to ongoing
- 5) LEVOTHYROXINE (LEVOTHYROXINE) --/--/1970 to ongoing
- 6) SPIRONOLACTONE (SPIRONOLACTONE) --/--/2016 to ongoing
- 7) PANTOPRAZOLE (PANTOPRAZOLE) --/--/2016 to ongoing
- 8) DICLOFENAC (DICLOFENAC) --/--/2018 to ongoing
- 9) ROPINIROLE (ROPINIROLE) --/--/2015 to ongoing
- 10) TRAMADOL (TRAMADOL) --/--/2017 to ongoing
- 11) GABAPENTIN (GABAPENTIN) --/--/2017 to ongoing
- 12) CLARITIN ALLERGIC (OXYMETAZOLINE HYDROCHLORIDE) --/--/2015 to ongoing

## 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.	09/03/2020 to 09/03/2020	Blinded	Blinded