

### A. PATIENT INFORMATION

<b>1. Patient Identifier</b> US3212182  In confidence	<b>2. Age at Time of Event:</b> 20 Years or <b>Date of Birth:</b> (b) (6)/2000	<b>3. Sex</b> <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	<b>4. Weight</b> 157.5 lbs or 71.4 kgs
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### B. ADVERSE EVENT OR PRODUCT PROBLEM

1. <input checked="" type="checkbox"/> <b>Adverse Event</b> and/or <input type="checkbox"/> <b>Product Problem</b> (e.g., defects/malfunctions)	
2. <b>Outcomes Attributed to Adverse Event</b> (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. <b>Date of Event</b> (mm/dd/yyyy) 08/17/2020	4. <b>Date of This Report</b> (mm/dd/yyyy) 11/22/2020

## 5. Describe Event or Problem

Drug exposure before pregnancy [Drug exposure before pregnancy]

### Case Description:

This 20-year-old, Hispanic, female subject (US3212182) 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 became pregnant.

The subject's medical history, as provided by the investigator, included mild asthma and appendectomy. The subject had no prior history of pregnancy. Concomitant medications reported included albuterol. continued in additional info section...

## 6. Relevant Tests/Laboratory Data, Including Dates

#1 08/14/2020 Pregnancy test urine (continued)  
#2 09/11/2020 Pregnancy test urine (continued)

7. **Other Relevant History, Including Preexisting Medical Conditions** (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Race: Unknown

#1 Pregnancy Date of LMP (MM-DD-YYYY) 08/12/2020  
#2 --/--/2002 to Ongoing, Current Condition, Asthma (mild)  
#3 --/--/2016 to --/--/2016, Procedure, Appendicectomy

### C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)		
#1. mRNA-1273 vs Placebo (Code not broken)		
#2.		
2. Dose, Frequency & Route Used		3. Therapy Dates (if unknown, give duration) from/to (or best estimate)
#1. Blinded, Information withheld.		#1. 08/14/2020 to 08/14/2020
#2.		#2.
4. Diagnosis for Use (Indication)		5. Event Abated After Use Stopped or Dose Reduced?
#1. COVID-19 (Continued)		
#2.		#1. <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't Apply
6. Lot #	7. Exp. Date	#2. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#1. Blinded	#1. Blinded	8. Event Reappeared After Reintroduction?
#2.	#2.	
9. NDC# or Unique ID		#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
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)		
1) ALBUTEROL /00139501/ (ALBUTEROL /00139501/) --/--/2002		
continued in additional info section...		

### G. ALL MANUFACTURERS

1. <b>Contact Office (and Manufacturing Site for Devices)</b>		2. <b>Phone Number</b> 617-335-1804
Name ModernaTX, Inc. David Martin MD.		<b>3. Report Source</b> (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: _____ _____ _____ _____
Address 200 Technology Square Cambridge, MA 02139 United States of America		
Email Address		
<b>4. Date Received by Manufacturer</b> (mm/dd/yyyy)  09/11/2020	<b>5. (A)NDA #</b> _____  IND #      019635  BLA #      _____  PMA/ 510(k) # _____  Combination Product <input type="checkbox"/> Yes Pre-1938 <input type="checkbox"/> Yes OTC Product <input type="checkbox"/> Yes	
<b>6. If IND, Give Protocol #</b> mRNA-1273-P301		
<b>7. Type of Report</b> (Check all that apply)  <input type="checkbox"/> 5-day <input type="checkbox"/> 30-day <input type="checkbox"/> 7-day <input type="checkbox"/> Periodic <input type="checkbox"/> 10-day <input type="checkbox"/> Initial <input type="checkbox"/> 15-day <input checked="" type="checkbox"/> Follow-up #1		
<b>9. Manufacturer Report Number</b> (b) (6)	<b>8. Adverse Event Term(s)</b> Drug exposure before pregnancy	

### E. INITIAL REPORTER

<b>1. Name and Address</b> Dr. Vicki Miller ClinSearch, LLC Chattanooga, Tennessee UNITED STATES		
<b>Phone #</b> (b) (6)	<b>Email Address</b> (b) (6) @dmclinicalresearch.com	
<b>2. Health Professional?</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<b>3. Occupation</b> Physician	<b>4. Initial Reporter Also Sent Report to FDA</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown

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)**

On 14 Aug 2020, the subject had a negative urine pregnancy test as part of pre-dose procedure. The subject received the first dose of intramuscular mRNA-1273 or placebo on 14 Aug 2020. There were no additional doses administered.

On 11 Sep 2020, the subject had a positive urine pregnancy test. She was using condoms with spermicide as contraceptive method. The first day of the subject's last menstrual period was 12 Aug 2020. The estimated date of conception was 17 Aug 2020 and the due date was estimated as May 2021.

Study drug was withdrawn as a result of the pregnancy.

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

Company Comment: This case concerns a 20-year-old, Hispanic, female subject using condoms with spermicide as contraceptive method, who experienced an unexpected event of pregnancy. The event occurred 27 days after study vaccine administration. Action taken with regards to study vaccine was withdrawn. 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	08/14/2020	Pregnancy test urine Negative		
2	09/11/2020	Pregnancy test urine Positive		

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

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

C10. CONCOMITANT MEDICAL PRODUCTS (Continued)  
to ongoing