US3912241 (Prod: Synexus - Optimal Research - Austin)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:20:52

All time stamps listed in this document are displayed in GMT

Participant ID | US3912241

mRNA-1273-P301 Completion Guidelines

US3912241

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **19 Feb 2021 17:22:19**

Generated On: 10 Jun 2021 10:20:52

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	SCRN

US3912241

Folder: Screening

Form: Demographics

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Date of Birth (MMM yyyy)	(b) (6) 1960
Age	59
Age Units	YEARS
Age (Derived)	59
Sex	Female ⬭
	Male ⬤
Ethnicity	Hispanic or Latino ⬭
	Not Hispanic or Latino ⬤
	Not Reported ⬭
	Unknown ⬭

Race (Check All That Apply)

White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

US3912241

Folder: Screening

Form: Enrollment

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Date of Informed Consent *(dd MMM yyyy)*	12 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020

Protocol Version

- Amendment 1 ◯
- Amendment 2 ◯
- Amendment 3 ◯
- Amendment 4 ⬤
- Amendment 5 ◯

Was participant enrolled in the study?

- Yes ⬤
- No ◯

If No, indicate reason for screen fail

- Withdrew Consent ◯
- Inclusion/Exclusion ◯
- Cohort Full ◯
- Other ◯

If reason for screen fail is Other, specify _____

Was this participant screened previously?

- Yes ◯
- No ⬤

If Yes, previous participant number _____

Enrollment Trigger 1

US3912241

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Did the participant meet all eligibility criteria?   Yes ●

                                                                      No ○

Were any significant conditions reported?　　　　Yes ⬤

No ◯

US3912241

Folder: Screening

Form: Medical History (1)

Data signed: ▨ (b) (4) ▨ **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Condition	GENERAL BODY ACHES
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Condition	ALLERGY TO ORANGES- ITCHY ALL OVER
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ●
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3912241

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Condition	ALLERGY TO TOMATOES-ITCHY ALL OVER
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3912241

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Condition	SCHIZOPHRENIA PSYCHOTIC DISORDER
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

US3912241

Folder: Screening

Form: Vital Signs

Data signed: ▨ (b) (4) ▨ 19 Feb 2021 17:22:19

Generated On: 10 Jun 2021 10:20:52

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	12 OCT 2020
Time of assessment *(00:00-23:59)*	09:36 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 09:36
Height *(xxx.x)*	68.5 in
Weight *(xxx.x)*	219.0 lb
BMI *(xxx.x)*	32.88311 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ○
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3912241

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Was the physical examination performed?   Yes ●

No ○

Date of examination *(dd MMM yyyy)*   12 OCT 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3912241
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) 19 Feb 2021 17:22:18
Generated On: 10 Jun 2021 10:20:52

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ⚪ No ⬤
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ⚪ No ⬤
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ⚪ No ⬤
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ⚪ No ⬤
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ⚪ No ⬤
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ⚪ No ⬤
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ⚪ No ⬤
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ⚪ No ⬤
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ⚪ No ⬤
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ⚪ No ⬤
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ⚪ No ⬤
Other	Yes ⬤ No ⚪
Specify	N/A

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False

Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **19 Feb 2021 17:22:18**
Generated On: 10 Jun 2021 10:20:52

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

US3912241

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) **19 Feb 2021 17:22:19**

Generated On: 10 Jun 2021 10:20:52

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT1

US3912241

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **19 Feb 2021 17:22:19**

Generated On: 10 Jun 2021 10:20:52

What was the date of randomization? *(dd MMM yyyy)*	12 OCT 2020
What was the participant's randomization number?	116725

In what Cohort was the participant enrolled?

- ● >=18 and <65 years and not at risk
- ○ >=18 and <65 years and at risk
- ○ >=65 years

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)	Yes ○ No ●
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)	Yes ○ No ●
Severe obesity (body mass index > or = 40kg/m2)	Yes ○ No ●
Diabetes (Type I, Type 2, or gestational)	Yes ○ No ●
Liver Disease	Yes ○ No ●
Human Immunodeficiency Virus (HIV) infection	Yes ○ No ●

US3912241
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **19 Feb 2021 17:22:19**
Generated On: 10 Jun 2021 10:20:52

Height	ND - Not Done
Weight	ND - Not Done

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **19 Feb 2021 17:22:19**

Generated On: 10 Jun 2021 10:20:52

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	12 OCT 2020
Time of assessment *(00:00-23:59)*	09:36 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 09:36
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	69 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	95 mmHg
Diastolic Blood Pressure units	MMHG

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **19 Feb 2021 17:22:19**

Generated On: 10 Jun 2021 10:20:52

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	12 OCT 2020
Time of assessment *(00:00-23:59)*	11:53 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 11:53
Temperature *(xxx.x)*	36.9 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	97 mmHg
Diastolic Blood Pressure units	MMHG

US3912241

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **19 Feb 2021 17:22:19**

Generated On: 10 Jun 2021 10:20:52

Was the physical examination performed?

Yes ◯

No ⬤

Date of examination *(dd MMM yyyy)*

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

Was study treatment given?	Yes ⬤
	No ◯

If No, reason not given	
	Participant declined due to Adverse Event ◯
	Physician withheld dose due to Adverse Event ◯
	Death ◯
	Lost To Follow-Up ◯
	Physician Decision ◯
	Pregnancy ◯
	Protocol Deviation ◯
	Study Terminated by Sponsor ◯
	Withdrawal of Consent by Participant ◯
	Confirmed COVID-19 ◯
	Other ◯

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	12 OCT 2020
What was the treatment time? *(00:00-23:59)*	11:17 (24 HR)
Treatment Date and Time (derived)	12 OCT 2020 11:17
Which arm was used to give treatment?	Left Arm ⬤
	Right Arm ◯
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-3511139

Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **19 Feb 2021 17:22:19**
Generated On: 10 Jun 2021 10:20:52

Was the sample collected?	Yes ⬤
	No ◯

Collection date *(dd MMM yyyy)*	12 OCT 2020
Collection time *(00:00-23:59)*	10:38 (24 HR)
Collection date and time (derived)	12 OCT 2020 10:38

US3912241

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **19 Feb 2021 17:22:19**

Generated On: 10 Jun 2021 10:20:52

Collection date *(dd MMM yyyy)*   12 OCT 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:45	12 OCT 2020 10:45
Nasopharyngeal Swab 2	No		

US3912241

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 17:22:19**

Generated On: 10 Jun 2021 10:20:52

Is the participant continuing to the next visit?   Yes ⬤

                                                                   No ◯

Continuing Flag   1

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	12 OCT 2020 12:02
PC Open Date & Time	12 OCT 2020 11:37
PC Close Date & Time	12 OCT 2020 14:07

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	12 OCT 2020 20:51
PC Open Date & Time	12 OCT 2020 15:02
PC Close Date & Time	13 OCT 2020 11:59

US3912241
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	13 OCT 2020 15:17
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	98.0 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	14 OCT 2020 12:03
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ⬤
	No ◯
Please record your **TEMPERATURE in °F**	97.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯
	No ⬤

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	15 OCT 2020 13:48
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	98.0 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	16 OCT 2020 16:39
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	96.5 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	17 OCT 2020 22:09
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	19 OCT 2020 06:36
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	12 OCT 2020 12:02
PC Open Date & Time	12 OCT 2020 11:37
PC Close Date & Time	12 OCT 2020 14:07

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	12 OCT 2020 20:52
PC Open Date & Time	12 OCT 2020 15:02
PC Close Date & Time	13 OCT 2020 11:59

FDA-CBER-2022-1614-3511152

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⭕ Does not interfere with activity ⚫ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ⭕ Any use of prescription pain reliever or prevents daily activity ⭕
Is there any **REDNESS AT INJECTION SITE**?	Yes ⭕ No ⚫
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ⭕ No ⚫
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⚫ Does not interfere with activity ⭕ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ⭕ Any use of prescription pain reliever or prevents daily activity ⭕
PC Time Stamp	13 OCT 2020 15:15
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	14 OCT 2020 12:02
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	15 OCT 2020 13:49
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

TIMEPOINT	DAY 5

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯

Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ●

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ●

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯

PC Time Stamp	16 OCT 2020 16:40
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	17 OCT 2020 22:10
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	19 OCT 2020 06:36
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)

HEADACHE

- None ⬤
- No interference with activity ⬭
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ⬭
- Any use of prescription pain reliever or prevents daily activity ⬭

FATIGUE

- None ⬤
- No interference with activity ⬭
- Some interference with activity ⬭
- Significant; prevents daily activity ⬭

MUSCLE ACHES ALL OVER BODY

- None ⬤
- No interference with activity ⬭
- Some interference with activity ⬭
- Significant; prevents daily activity ⬭

JOINT ACHES IN SEVERAL JOINTS

- None ⬤
- No interference with activity ⬭
- Some interference with activity ⬭
- Significant; prevents daily activity ⬭

NAUSEA/VOMITING

- None ⬤
- No interference with activity or 1-2 episodes/24 hours ⬭
- Some interference with activity or >2 episodes/24 hours ⬭
- Prevents daily activity, requires outpatient IV hydration ⬭

CHILLS

- None ⬤
- No interference with activity ⬭
- Some interference with activity not requiring medical attention ⬭
- Prevents daily activity and requires medical attention ⬭

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯

PC Time stamp	12 OCT 2020 12:03
PC Open Date & Time	12 OCT 2020 11:37
PC Close Date & Time	12 OCT 2020 14:07

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
HEADACHE	None ●
	No interference with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
FATIGUE	None ●
	No interference with activity ○
	Some interference with activity ○
	Significant; prevents daily activity ○
MUSCLE ACHES ALL OVER BODY	None ●
	No interference with activity ○
	Some interference with activity ○
	Significant; prevents daily activity ○
JOINT ACHES IN SEVERAL JOINTS	None ●
	No interference with activity ○
	Some interference with activity ○
	Significant; prevents daily activity ○
NAUSEA/VOMITING	None ●
	No interference with activity or 1-2 episodes/24 hours ○
	Some interference with activity or >2 episodes/24 hours ○
	Prevents daily activity, requires outpatient IV hydration ○
CHILLS	None ●
	No interference with activity ○
	Some interference with activity not requiring medical attention ○
	Prevents daily activity and requires medical attention ○

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:20:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	12 OCT 2020 20:53
PC Open Date & Time	12 OCT 2020 15:02
PC Close Date & Time	13 OCT 2020 11:59

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 2

HEADACHE
- None ○
- No interference with activity ⬤
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
- Any use of prescription pain reliever or prevents daily activity ○

FATIGUE
- None ○
- No interference with activity ⬤
- Some interference with activity ○
- Significant; prevents daily activity ○

MUSCLE ACHES ALL OVER BODY
- None ⬤
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

JOINT ACHES IN SEVERAL JOINTS
- None ○
- No interference with activity ⬤
- Some interference with activity ○
- Significant; prevents daily activity ○

NAUSEA/VOMITING
- None ⬤
- No interference with activity or 1-2 episodes/24 hours ○
- Some interference with activity or >2 episodes/24 hours ○
- Prevents daily activity, requires outpatient IV hydration ○

CHILLS
- None ⬤
- No interference with activity ○
- Some interference with activity not requiring medical attention ○
- Prevents daily activity and requires medical attention ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — No ⬤

	Yes ◯
PC Time stamp	13 OCT 2020 15:16
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 3

HEADACHE

None	●
No interference with activity	○
Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity	○
Any use of prescription pain reliever or prevents daily activity	○

FATIGUE

None	●
No interference with activity	○
Some interference with activity	○
Significant; prevents daily activity	○

MUSCLE ACHES ALL OVER BODY

None	●
No interference with activity	○
Some interference with activity	○
Significant; prevents daily activity	○

JOINT ACHES IN SEVERAL JOINTS

None	●
No interference with activity	○
Some interference with activity	○
Significant; prevents daily activity	○

NAUSEA/VOMITING

None	●
No interference with activity or 1-2 episodes/24 hours	○
Some interference with activity or >2 episodes/24 hours	○
Prevents daily activity, requires outpatient IV hydration	○

CHILLS

None	●
No interference with activity	○
Some interference with activity not requiring medical attention	○
Prevents daily activity and requires medical attention	○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●

	Yes ◯
PC Time stamp	14 OCT 2020 12:02
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 4
HEADACHE	None ◯
	No interference with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
FATIGUE	None ◯
	No interference with activity ◯
	Some interference with activity ◯
	Significant; prevents daily activity ◯
MUSCLE ACHES ALL OVER BODY	None ◯
	No interference with activity ◯
	Some interference with activity ◯
	Significant; prevents daily activity ◯
JOINT ACHES IN SEVERAL JOINTS	None ◯
	No interference with activity ◯
	Some interference with activity ◯
	Significant; prevents daily activity ◯
NAUSEA/VOMITING	None ◯
	No interference with activity or 1-2 episodes/24 hours ◯
	Some interference with activity or >2 episodes/24 hours ◯
	Prevents daily activity, requires outpatient IV hydration ◯
CHILLS	None ◯
	No interference with activity ◯
	Some interference with activity not requiring medical attention ◯
	Prevents daily activity and requires medical attention ◯
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ◯

	Yes ◯
PC Time stamp	
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 5

HEADACHE

None ●
No interference with activity ○
Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
Any use of prescription pain reliever or prevents daily activity ○

FATIGUE

None ●
No interference with activity ○
Some interference with activity ○
Significant; prevents daily activity ○

MUSCLE ACHES ALL OVER BODY

None ●
No interference with activity ○
Some interference with activity ○
Significant; prevents daily activity ○

JOINT ACHES IN SEVERAL JOINTS

None ●
No interference with activity ○
Some interference with activity ○
Significant; prevents daily activity ○

NAUSEA/VOMITING

None ●
No interference with activity or 1-2 episodes/24 hours ○
Some interference with activity or >2 episodes/24 hours ○
Prevents daily activity, requires outpatient IV hydration ○

CHILLS

None ●
No interference with activity ○
Some interference with activity not requiring medical attention ○
Prevents daily activity and requires medical attention ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? No ●

FDA-CBER-2022-1614-3511169

	Yes ◯
PC Time stamp	16 OCT 2020 16:40
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 6

HEADACHE

- None ●
- No interference with activity ○
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
- Any use of prescription pain reliever or prevents daily activity ○

FATIGUE

- None ○
- No interference with activity ●
- Some interference with activity ○
- Significant; prevents daily activity ○

MUSCLE ACHES ALL OVER BODY

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

JOINT ACHES IN SEVERAL JOINTS

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

NAUSEA/VOMITING

- None ●
- No interference with activity or 1-2 episodes/24 hours ○
- Some interference with activity or >2 episodes/24 hours ○
- Prevents daily activity, requires outpatient IV hydration ○

CHILLS

- None ●
- No interference with activity ○
- Some interference with activity not requiring medical attention ○
- Prevents daily activity and requires medical attention ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — No ●

	Yes ◯
PC Time stamp	17 OCT 2020 22:11
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 7

HEADACHE

- None ●
- No interference with activity ○
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
- Any use of prescription pain reliever or prevents daily activity ○

FATIGUE

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

MUSCLE ACHES ALL OVER BODY

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

JOINT ACHES IN SEVERAL JOINTS

- None ●
- No interference with activity ○
- Some interference with activity ○
- Significant; prevents daily activity ○

NAUSEA/VOMITING

- None ●
- No interference with activity or 1-2 episodes/24 hours ○
- Some interference with activity or >2 episodes/24 hours ○
- Prevents daily activity, requires outpatient IV hydration ○

CHILLS

- None ●
- No interference with activity ○
- Some interference with activity not requiring medical attention ○
- Prevents daily activity and requires medical attention ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? — No ●

Yes ◯

PC Time stamp	19 OCT 2020 06:37
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3912241
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **19 Feb 2021 17:22:18**
Generated On: 10 Jun 2021 10:20:52

Was Contact Attempted?   Yes ●

                                                                         No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*   19 OCT 2020

Please select one status for the follow-up contact   Contact Made ●

                                                            Contact Not Made ○

Comments

If Contact Not Made, please provide Comments _____

US3912241

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Is the participant continuing to the next visit?   Yes ⬤

                                                                      No ◯

Continuing Flag   1

US3912241
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **19 Feb 2021 17:22:18**
Generated On: 10 Jun 2021 10:20:52

| Was Contact Attempted? | Yes ⬤ |
| | No ◯ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 26 OCT 2020 |

| Please select one status for the follow-up contact | Contact Made ⬤ |
| | Contact Not Made ◯ |

Comments

If Contact Not Made, please provide Comments _____

US3912241

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag 1

US3912241

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

| Was Contact Attempted? | Yes ● |
| | No ◯ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 2 NOV 2020 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ◯ |

Comments

If Contact Not Made, please provide Comments

US3912241

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Is the participant continuing to the next visit?   Yes ●

                                                                     No ○

Continuing Flag   1

US3912241
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **19 Feb 2021 17:22:19**
Generated On: 10 Jun 2021 10:20:52

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	09 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT2

US3912241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **19 Feb 2021 17:22:19**

Generated On: 10 Jun 2021 10:20:52

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	9 NOV 2020
Time of assessment *(00:00-23:59)*	09:44 (24 HR)
Vital Signs Date and Time (derived)	9 NOV 2020 09:44
Temperature *(xxx.x)*	98.9 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	86 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	82 mmHg
Diastolic Blood Pressure units	MMHG

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **19 Feb 2021 17:22:19**

Generated On: 10 Jun 2021 10:20:52

Timepoint	Pre-Dose	◯
	Post-Dose	⬤
Were vital signs assessed?	Yes	◯
	No	⬤

Date of assessment *(dd MMM yyyy)* _____

Time of assessment *(00:00-23:59)* _____

Vital Signs Date and Time (derived) _____

Temperature *(xxx.x)* _____

Route of measurement	Oral	◯
	Axillary	◯
	Other	◯

If Other, specify _____

Pulse *(xxx)* _____

Pulse units _____

Respiratory Rate *(xxx)* _____

Respiratory Rate units _____

Systolic Blood Pressure *(xxx)* _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure *(xxx)* _____

Diastolic Blood Pressure units _____

US3912241

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **19 Feb 2021 17:22:19**

Generated On: 10 Jun 2021 10:20:52

Was the physical examination performed?　　　　　　　　Yes ●

No ◯

Date of examination *(dd MMM yyyy)*　　　　　　　　　　9 NOV 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

Was study treatment given?   Yes ◯

                                                                  No ⬤

If No, reason not given   Participant declined due to ◯
                                                 Adverse Event

                                        Physician withheld dose due to ⬤
                                                 Adverse Event

                                                          Death ◯

                                              Lost To Follow-Up ◯

                                              Physician Decision ◯

                                                     Pregnancy ◯

                                              Protocol Deviation ◯

                                     Study Terminated by Sponsor ◯

                                       Withdrawal of Consent by ◯
                                                   Participant

                                         Confirmed COVID-19 ◯

                                                         Other ◯

If reason is Physician Decision, Withdrawal of Consent by
Participant, Protocol Deviation, or Other, specify   _____

What was the study treatment?   _____

What was the treatment date? *(dd MMM yyyy)*   _____

What was the treatment time? *(00:00-23:59)*   _____

Treatment Date and Time (derived)   _____

Which arm was used to give treatment?   Left Arm ◯

                                                      Right Arm ◯

What was the frequency of the study treatment dosing?   _____

What was the route of administration for the study treatment?   _____

US3912241

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **19 Feb 2021 17:22:19**

Generated On: 10 Jun 2021 10:20:52

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	9 NOV 2020
Collection time *(00:00-23:59)*	10:50 (24 HR)
Collection date and time (derived)	9 NOV 2020 10:50

US3912241

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **19 Feb 2021 17:22:19**

Generated On: 10 Jun 2021 10:20:52

Collection date *(dd MMM yyyy)*			9 NOV 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:55	9 NOV 2020 10:55
Nasopharyngeal Swab 2	No		

Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4)   **19 Feb 2021 17:22:19**
Generated On: 10 Jun 2021 10:20:52

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3912241
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **19 Feb 2021 17:22:18**
Generated On: 10 Jun 2021 10:20:52

Was Contact Attempted?   Yes ●

                                                                    No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*   16 NOV 2020

Please select one status for the follow-up contact   Contact Made ●

                                                     Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3912241

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Is the participant continuing to the next visit?   Yes ⬤

     No ◯

Continuing Flag   1

US3912241

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 23 NOV 2020 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments

US3912241

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Is the participant continuing to the next visit?   Yes ⬤

                                                                                          No ◯

Continuing Flag   1

US3912241

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	30 NOV 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3912241

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Is the participant continuing to the next visit?   Yes ●

                                                                                     No ◯

Continuing Flag   1

US3912241

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) **19 Feb 2021 17:22:19**

Generated On: 10 Jun 2021 10:20:52

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	04 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT3

US3912241

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **19 Feb 2021 17:22:19**

Generated On: 10 Jun 2021 10:20:52

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	04 DEC 2020
Time of assessment *(00:00-23:59)*	13:23 (24 HR)
Vital Signs Date and Time (derived)	04 DEC 2020 13:23
Temperature *(xxx.x)*	36.9 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3912241

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) **19 Feb 2021 17:22:19**

Generated On: 10 Jun 2021 10:20:52

Was the physical examination performed? Yes ◯

No ⬤

Date of examination *(dd MMM yyyy)* _____

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **19 Feb 2021 17:22:19**

Generated On: 10 Jun 2021 10:20:52

Was the sample collected?	Yes ⬤
	No ◯

Collection date *(dd MMM yyyy)*	04 DEC 2020
Collection time *(00:00-23:59)*	14:37 (24 HR)
Collection date and time (derived)	04 DEC 2020 14:37

US3912241

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 17:22:19**

Generated On: 10 Jun 2021 10:20:52

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag   1

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 15:06:51
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚫
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚫ Yes ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚫ Yes ⚪
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚫
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚫
Date and time of submission	16 DEC 2020 00:42:22
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 DEC 2020 02:39:20
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚫
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚫ Yes ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚫ Yes ⚪
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚫
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚫
Date and time of submission	01 JAN 2021 23:23:23
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 14:48:09
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 16:21:53
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 19:44:26
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 JAN 2021 00:22:46
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 FEB 2021 00:03:46
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3912241

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:20:52

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission

US3912241

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Was Contact Attempted?   Yes ●

                                                                          No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*   4 JAN 2021

Please select one status for the follow-up contact   Contact Made ●

                                                        Contact Not Made ○

Comments

If Contact Not Made, please provide Comments   _____

US3912241

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Is the participant continuing to the next visit?   Yes ●

                                                                           No ○

Continuing Flag   1

US3912241
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:20:52

Was Contact Attempted?	Yes ◯
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)* _____

Please select one status for the follow-up contact	Contact Made ◯
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments _____

Is the participant continuing to the next visit?   Yes ◯

No ◯

Continuing Flag

US3912241
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 10 Jun 2021 10:20:52

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	

Type of Contact	Clinic Visit - Scheduled ⚪
	Clinical Visit - Unscheduled ⚪
	Safety Call ⚪
	Convalescent Tele-visit ⚪

Has the subject reported symptoms of SARS-COV-2?	Yes ⚪
	No ⚪

FDA-CBER-2022-1614-3511214

| Generate Next COVID-19 Assessment | Yes ◯ |
| | No ◯ |

Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **19 Feb 2021 17:22:18**
Generated On: 10 Jun 2021 10:20:52

| Was this visit performed? | Yes ● |
| | No ○ |

Visit date (dd MMM yyyy)	2 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

| Folder OID | UNBLND_DECIDE |

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) **12 Mar 2021 19:16:46**

Generated On: 10 Jun 2021 10:20:52

Date of updated informed consent *(dd MMM yyyy)*	2 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ●
	No ○
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ○
	Amendment 6 or later ●
Date of unblinding *(dd MMM yyyy)*	2 FEB 2021
Participant randomization assignment	mRNA-1273 ○
	Placebo ●
Actual Dose 1	mRNA-1273 ○
	Placebo ●
	Not Administered ○
Actual Dose 2	mRNA-1273 ○
	Placebo ●
	Not Administered ○
Will participant receive mRNA-1273?	Yes ○
	No ●
Placebo Only Flag	1
Continuing with mRNA-1273	

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	2 FEB 2021
Collection time *(00:00-23:59)*	12:18 (24 HR)
Collection date and time (derived)	2 FEB 2021 12:18

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4)   **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	2 FEB 2021
Collection time *(00:00 - 23:59)*	12:22
Collection Date and Time (derived)	2 FEB 2021 12:22

US3912241

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Did the participant experience any adverse events?   Yes ⬤

No ◯

If Yes, enter details on the Adverse Events form.

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **24 Mar 2021 22:48:57**

Generated On: 10 Jun 2021 10:20:52

AEID	
Adverse event	GENERALIZED WEAKNESS
Was this a medically-attended AE?	Yes ⬤
	No ◯
Was this a Solicited Adverse Reaction?	Yes ◯
	No ⬤
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ◯
	No ⬤
Start date *(dd MMM yyyy)*	3 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	06 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ◯
	Grade 3/Severe ◯
	Grade 4 ⬤
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
	Not Related ◯
	Related ●
	Not Applicable ◯

Relationship to Study Procedure	
	Not Related ●
	Related ◯
	Not Applicable ◯

Action taken with investigational product	
	None ●
	Dose Delayed ◯
	Investigational Product Withdrawn ◯
	Not Applicable ◯

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome	
	Fatal ◯
	Not Recovered/Not Resolved ◯
	Recovered/Resolved ●
	Recovered/Resolved with Sequelae ◯
	Recovering/Resolving ◯
	Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) **24 Mar 2021 22:48:57**

Generated On: 10 Jun 2021 10:20:52

AEID	
Adverse event	CHEST PAIN (PLEURAL)
Was this a medically-attended AE?	Yes ●
	No ○
Was this a Solicited Adverse Reaction?	Yes ○
	No ●
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ○
	No ●
Start date *(dd MMM yyyy)*	03 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ○
	No ●
If not Ongoing, end date *(dd MMM yyyy)*	05 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ●
	Grade 2/Moderate ○
	Grade 3/Severe ○
	Grade 4 ○
Is the adverse event serious?	Yes ○
	No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○
	No ○
	Unknown ○
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ◯
- Related ⬤
- Not Applicable ◯

Relationship to Study Procedure

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Action taken with investigational product

- None ⬤
- Dose Delayed ◯
- Investigational Product Withdrawn ◯
- Not Applicable ◯

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome

- Fatal ◯
- Not Recovered/Not Resolved ◯
- Recovered/Resolved ⬤
- Recovered/Resolved with Sequelae ◯
- Recovering/Resolving ◯
- Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

FDA-CBER-2022-1614-3511224

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) **24 Mar 2021 22:48:57**

Generated On: 10 Jun 2021 10:20:52

AEID	USA-US211-2020-MRNA-1273-P30 1000004
Adverse event	PULMONARY EMBOLISM, LLL

Was this a medically-attended AE? — Yes ● No ○

Was this a Solicited Adverse Reaction? — Yes ○ No ●

Is this event a confirmed diagnosis of Symptomatic Covid-19? — Yes ○ No ●

Start date *(dd MMM yyyy)*	03 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing? — Yes ○ No ●

If not Ongoing, end date *(dd MMM yyyy)*	9 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity — Grade 1/Mild ○ Grade 2/Moderate ○ Grade 3/Severe ○ Grade 4 ●

Is the adverse event serious? — Yes ● No ○

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	4 NOV 2020
Hospital Discharge Date *(dd MMM yyyy)*	05 NOV 2020

Admitted to ICU? — Yes ○ No ● Unknown ○

PRODUCTION RELEASE (v12.003 EAB) (1725)

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ●
- Related ○
- Not Applicable ○

Relationship to Study Procedure

- Not Related ●
- Related ○
- Not Applicable ○

Action taken with investigational product

- None ○
- Dose Delayed ○
- Investigational Product Withdrawn ●
- Not Applicable ○

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome

- Fatal ○
- Not Recovered/Not Resolved ○
- Recovered/Resolved ●
- Recovered/Resolved with Sequelae ○
- Recovering/Resolving ○
- Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

FDA-CBER-2022-1614-3511226

SUBJECT CALLED STUDY SITE ON THE MORNING OF 04 NOVEMBER 2020 TO REPORT THAT HE WAS FEELING GENERALIZED WEAKNESS AND CHEST PAIN. SUBJECT CALLED THE HOSPITAL TO REPORT THESE SYMPTOMS AND WAS ADVISED TO STAY HOME. SEVERAL HOURS LATER WHEN SUBJECT WAS STILL EXPERIENCING SYMPTOMS HE CALLED EMS AND WAS TRANSPORTED TO THE HOSPITAL VIA AMBULANCE. SUBJECT CALLED SITE AGAIN IN THE AFTERNOON TO REPORT THAT HE HAS A BLOOD CLOT IN HIS LUNGS AND IS TAKING A BLOOD THINNER. HE STATES THAT HE WAS ADMITTED TO THE HOSPITAL. SUBJECT WAS IN GOOD SPIRITS AND TALKATIVE. HE REPORTED FEELING BETTER. SITE STAFF ASKED SUBJECT TO HAVE THE ATTENDING PHYSICIAN CALL PI WHEN AVAILABLE.

Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) **24 Mar 2021 22:48:57**

Generated On: 10 Jun 2021 10:20:52

AEID	USA-US211-2020-MRNA-1273-P30 1000007
Adverse event	WORSENING OF SCHIZOPHRENIA PSYCHOTIC DISORDER

Was this a medically-attended AE?　　Yes ●　No ○

Was this a Solicited Adverse Reaction?　　Yes ○　No ●

Is this event a confirmed diagnosis of Symptomatic Covid-19?　　Yes ○　No ●

Start date *(dd MMM yyyy)*	1 DEC 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?　　Yes ○　No ●

If not Ongoing, end date *(dd MMM yyyy)*	4 DEC 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity　　Grade 1/Mild ○　Grade 2/Moderate ○　Grade 3/Severe ●　Grade 4 ○

Is the adverse event serious?　　Yes ●　No ○

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	1 DEC 2020
Hospital Discharge Date *(dd MMM yyyy)*	4 DEC 2020

Admitted to ICU?　　Yes ○　No ●

PRODUCTION RELEASE (v12.003 EAB) (1725)

	Unknown ⚪
Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ⚫
	Related ⚪
	Not Applicable ⚪
Relationship to Study Procedure	Not Related ⚫
	Related ⚪
	Not Applicable ⚪
Action taken with investigational product	None ⚪
	Dose Delayed ⚪
	Investigational Product Withdrawn ⚪
	Not Applicable ⚫

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ⚪
	Not Recovered/Not Resolved ⚪
	Recovered/Resolved ⚫
	Recovered/Resolved with Sequelae ⚪
	Recovering/Resolving ⚪
	Unknown ⚪

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

FDA-CBER-2022-1614-3511229

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) **24 Mar 2021 22:48:57**

Generated On: 10 Jun 2021 10:20:52

SUBJECT ARRIVED FOR DAY 57 VISIT AND REPORTED TO STAFF THAT HE HAD JUST BEEN RELEASED FROM CROSS CREEK HOSPITAL WHICH IS A PSYCHIATRIC HOSPITAL. SUBJECT BROUGHT HIS DISCHARGE PAPERWORK AND SITE WAS ABLE TO OBTAIN A COPY. IT STATES THAT SUBJECT WAS ADMITTED DUE TO BEING A DANGER TO HIMSELF. HIS BEHAVIORAL HEALTH DIAGNOSIS WAS SCHIZOPHRENIA PSYCHOTIC DISORDER. SUBJECT DENIED THIS AS MEDICAL HISTORY, HOWEVER, AFTER FURTHER QUESTIONING SUBJECT STATED THAT HE HAS BEEN INSTITUTIONALIZED A TOTAL OF 4 TIMES SINCE 2006. SUBJECT DENIED BEING A DANGER TO HIMSELF. HE STATED THAT HE ADMITTED HIMSELF TO THE HOSPITAL TO GET AWAY FROM ALL OF THE PEOPLE AT HIS HOUSE. CONDITION ADDED TO MEDICAL HISTORY WITH A START DATE OF 2006. DETAILED RECORDS SURROUNDING THE IN PATIENT HOSPITALIZATION WERE REQUESTED.

Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) **24 Mar 2021 22:48:57**

Generated On: 10 Jun 2021 10:20:52

AEID	
Adverse event	DRY SKIN

Was this a medically-attended AE?
- Yes ○
- No ●

Was this a Solicited Adverse Reaction?
- Yes ○
- No ●

Is this event a confirmed diagnosis of Symptomatic Covid-19?
- Yes ○
- No ●

Start date *(dd MMM yyyy)*	21 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?
- Yes ●
- No ○

If not Ongoing, end date *(dd MMM yyyy)*	
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity
- Grade 1/Mild ●
- Grade 2/Moderate ○
- Grade 3/Severe ○
- Grade 4 ○

Is the adverse event serious?
- Yes ○
- No ●

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	

Admitted to ICU?
- Yes ○
- No ○
- Unknown ○

Number of Days in ICU	

FDA-CBER-2022-1614-3511231

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) **24 Mar 2021 22:48:57**

Generated On: 10 Jun 2021 10:20:52

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	Not Related	⬤
	Related	◯
	Not Applicable	◯

Relationship to Study Procedure	Not Related	⬤
	Related	◯
	Not Applicable	◯

Action taken with investigational product	None	◯
	Dose Delayed	◯
	Investigational Product Withdrawn	◯
	Not Applicable	⬤

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome	Fatal	◯
	Not Recovered/Not Resolved	⬤
	Recovered/Resolved	◯
	Recovered/Resolved with Sequelae	◯
	Recovering/Resolving	◯
	Unknown	◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Were any prior/concomitant medications and/or vaccinations taken?   Yes ⬤

No ◯

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Name of Medication	ASPIRIN

Prophylaxis	
	Yes ◯
	No ⬤

Indication	GENERALIZED BODY ACHES
Dose per administration	325

Dose unit	
	mg ◯
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ⬤
	capsule ◯
	puff ◯
	Other ◯

If dose unit is Other, specify _____

Frequency	
	once daily ◯
	twice daily ◯
	three times daily ◯
	four times daily ◯
	every other day ◯
	every week ◯
	every month ◯
	as needed ⬤
	once ◯
	unknown ◯
	other ◯

If frequency is Other, specify _____

Route of administration	
	Oral ⬤
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯
	Intraocular ◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

Intramuscular ◯

Respiratory (Inhalation) ◯

Intralesional ◯

Intraperiteoneal ◯

Nasal ◯

Vaginal ◯

Rectal ◯

Intravenous ◯

Intravenous Bolus ◯

Intravenous Drip ◯

Other ◯

If route of administration is Other, specify

Start date *(dd MMM yyyy)*   UN UNK 2000

Start date completely unknown   False

Ongoing?   Yes ⬤

No ◯

If not Ongoing, End date *(dd MMM yyyy)*

Was this medication taken for solicited event?   Yes ◯

No ⬤

Separate Dosage Number (derived)

Interval Dosage Unit Number (derived)

Interval Dosage Definition (derived)   802 ◯

803 ◯

804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Name of Medication	ENOXAPARIN SODIUM (LOVENOX)

Prophylaxis

Yes ◯
No ⬤

Indication	PULMONARY EMBOLISM
Dose per administration	100

Dose unit

mg ⬤
ug ◯
mL ◯
g ◯
IU ◯
tablet ◯
capsule ◯
puff ◯
Other ◯

If dose unit is Other, specify

Frequency

once daily ◯
twice daily ⬤
three times daily ◯
four times daily ◯
every other day ◯
every week ◯
every month ◯
as needed ◯
once ◯
unknown ◯
other ◯

If frequency is Other, specify

Route of administration

Oral ◯
Topical ◯
Subcutaneous ⬤
Transdermal ◯

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	04 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	05 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	KETOROLAC TROMETHAMINE

Prophylaxis

Yes ⚪
No ⚫

Indication	CHEST PAIN
Dose per administration	10

Dose unit

mg ⚫
ug ⚪
mL ⚪
g ⚪
IU ⚪
tablet ⚪
capsule ⚪
puff ⚪
Other ⚪

If dose unit is Other, specify _____

Frequency

once daily ⚪
twice daily ⚪
three times daily ⚪
four times daily ⚪
every other day ⚪
every week ⚪
every month ⚪
as needed ⚪
once ⚫
unknown ⚪
other ⚪

If frequency is Other, specify _____

Route of administration

Oral ⚪
Topical ⚪
Subcutaneous ⚪
Transdermal ⚪
Intraocular ⚪

FDA-CBER-2022-1614-3511238

Intramuscular	⚪
Respiratory (Inhalation)	⚪
Intralesional	⚪
Intraperiteoneal	⚪
Nasal	⚪
Vaginal	⚪
Rectal	⚪
Intravenous	⬤
Intravenous Bolus	⚪
Intravenous Drip	⚪
Other	⚪

If route of administration is Other, specify

Start date *(dd MMM yyyy)*   04 NOV 2020

Start date completely unknown   False

Ongoing?   Yes ⚪

    No ⬤

If not Ongoing, End date *(dd MMM yyyy)*   04 NOV 2020

Was this medication taken for solicited event?   Yes ⚪

    No ⬤

Separate Dosage Number (derived)

Interval Dosage Unit Number (derived)

Interval Dosage Definition (derived)   802 ⚪

    803 ⚪

    804 ⚪

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Name of Medication	IOPAMIDOL

Prophylaxis

Yes ◯

No ⬤

Indication	DIAGNOSTIC AGENT FOR CTA
Dose per administration	100

Dose unit

mg ◯

ug ◯

mL ⬤

g ◯

IU ◯

tablet ◯

capsule ◯

puff ◯

Other ◯

If dose unit is Other, specify

Frequency

once daily ◯

twice daily ◯

three times daily ◯

four times daily ◯

every other day ◯

every week ◯

every month ◯

as needed ◯

once ⬤

unknown ◯

other ◯

If frequency is Other, specify

Route of administration

Oral ◯

Topical ◯

Subcutaneous ◯

Transdermal ◯

Intraocular ◯

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	04 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	04 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Name of Medication	TYLENOL/ CODEINE #3
Prophylaxis	Yes ○
	No ●
Indication	CHEST PAIN
Dose per administration	300/30
Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ○
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ○
	unknown ○
	other ●
If frequency is Other, specify	1-2 TABLETS EVERY 6 HOURS AS NEEDED
Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○

PRODUCTION RELEASE (v12.003 EAB) (1725)

Intraocular ◯

Intramuscular ◯

Respiratory (Inhalation) ◯

Intralesional ◯

Intraperiteoneal ◯

Nasal ◯

Vaginal ◯

Rectal ◯

Intravenous ◯

Intravenous Bolus ◯

Intravenous Drip ◯

Other ◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	05 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	05 NOV 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4)   **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Name of Medication	APIXABAN (ELIQUIS)

Prophylaxis

Yes ○
No ●

Indication	PULMONARY EMBOLISM
Dose per administration	5

Dose unit

mg ●
ug ○
mL ○
g ○
IU ○
tablet ○
capsule ○
puff ○
Other ○

If dose unit is Other, specify _____

Frequency

once daily ○
twice daily ●
three times daily ○
four times daily ○
every other day ○
every week ○
every month ○
as needed ○
once ○
unknown ○
other ○

If frequency is Other, specify _____

Route of administration

Oral ●
Topical ○
Subcutaneous ○
Transdermal ○
Intraocular ○

PRODUCTION RELEASE (v12.003
EAB) (1725)

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	05 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

FDA-CBER-2022-1614-3511245

US3912241

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Were any concomitant procedures performed?   Yes ●

                                                             No ◯

If yes, please complete Concomitant Procedures form.

US3912241

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) **24 Mar 2021 22:48:57**

Generated On: 10 Jun 2021 10:20:52

Procedure/Surgery date (*dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
04 NOV 2020	DOPPLER ULTRASOUND	Diagnostic	
04 NOV 2020	CHEST X-RAY	Diagnostic	
04 NOV 2020	TRANSTHORACIC ECHOCARDIOGRAPHY	Diagnostic	
04 NOV 2020	ELECTROCARDIOGRAM	Diagnostic	

Date of dosing discontinuation (dd MMM yyyy)	04 NOV 2020
Primary reason for dosing discontinuation	AE (specify) ◯
	SAE (specify) ⬤
	Death ◯
	Lost To Follow-up ◯
	Physician decision (specify) ◯
	Pregnancy ◯
	Protocol deviation (specify) ◯
	Study Terminated By Sponsor ◯
	Withdrawal of consent by participant (specify) ◯
	Due to SARS-COV-2 ◯
	Other ◯
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	AE #3

US3912241

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: [(b) (4)] **19 Feb 2021 17:22:18**

Generated On: 10 Jun 2021 10:20:52

Date of study discontinuation/completion *(dd MMM yyyy)*	4 FEB 2021

Reason for discontinuation	
	AE (specify) ◯
	SAE (specify) ◯
	Complete ◯
	Death ◯
	Lost To Follow-up ◯
	Physician decision (specify) ●
	Pregnancy ◯
	Protocol deviation (specify) ◯
	Study Terminated By Sponsor ◯
	Withdrawal of consent by participant (specify) ◯
	Other ◯

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	SUBJECT WAS WITHDRAWN DUE TO HIS REFUSAL TO MEDICALLY MANAGE HIS MENTAL HEALTH (SCHIZOPHRENIA); REALIZING THAT THIS CONDITION WILL LIKELY WORSEN WITHOUT TREATMENT, SUBJECT WITHDRAWN.

If reason for discontinuation is Death, main cause of death	
	Adverse event ◯
	Unknown ◯
	Other ◯

If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	

Was autopsy performed?	
	Yes ◯
	No ◯
	Unknown ◯

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4)   **25 Mar 2021 17:49:46**

Generated On: 10 Jun 2021 10:20:52

SAEID	USA-US211-2020-MRNA-1273-P30 1000004
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) **25 Mar 2021 17:49:46**

Generated On: 10 Jun 2021 10:20:52

SAEID	USA-US211-2020-MRNA-1273-P30 1000004
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	05/NOV/2020 14:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) **25 Mar 2021 17:49:46**

Generated On: 10 Jun 2021 10:20:52

SAEID	USA-US211-2020-MRNA-1273-P30 1000004
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	09/NOV/2020 14:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) **25 Mar 2021 17:49:46**

Generated On: 10 Jun 2021 10:20:52

SAEID	USA-US211-2020-MRNA-1273-P30 1000004
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	13/NOV/2020 16:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

SAEID	USA-US211-2020-MRNA-1273-P30 1000004
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ○ / No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ○ / No ●
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	17/NOV/2020 08:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) **25 Mar 2021 17:49:46**

Generated On: 10 Jun 2021 10:20:52

SAEID	USA-US211-2020-MRNA-1273-P30 1000004
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	23/NOV/2020 15:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form (6)
Data signed: ▓▓ (b) (4) ▓▓ **25 Mar 2021 17:49:46**
Generated On: 10 Jun 2021 10:20:52

SAEID	USA-US211-2020-MRNA-1273-P30 1000004
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	21/DEC/2020 10:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Data signed: (b) (4) **25 Mar 2021 17:49:46**

Generated On: 10 Jun 2021 10:20:52

SAEID	USA-US211-2020-MRNA-1273-P30 1000004
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	25/MAR/2021 10:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: [(b) (4)] **25 Mar 2021 17:49:46**

Generated On: 10 Jun 2021 10:20:52

SAEID	USA-US211-2020-MRNA-1273-P30 1000007
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) **25 Mar 2021 17:49:46**

Generated On: 10 Jun 2021 10:20:52

SAEID	USA-US211-2020-MRNA-1273-P30 1000007
Serious	Yes ● / No ○
Death	Yes ○ / No ●
Life threatening	Yes ○ / No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● / No ○
Persistent or significant disability or incapacity	Yes ○ / No ●
Congenital anomaly or birth defect	Yes ○ / No ●
Other medically important event	Yes ○ / No ●
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	06/DEC/2020 17:45
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) **25 Mar 2021 17:49:46**

Generated On: 10 Jun 2021 10:20:52

SAEID	USA-US211-2020-MRNA-1273-P30 1000007
Serious	Yes ●
	No ○
Death	Yes ○
	No ●
Life threatening	Yes ○
	No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ●
	No ○
Persistent or significant disability or incapacity	Yes ○
	No ●
Congenital anomaly or birth defect	Yes ○
	No ●
Other medically important event	Yes ○
	No ●
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	23/DEC/2020 08:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) **25 Mar 2021 17:49:46**

Generated On: 10 Jun 2021 10:20:52

SAEID	USA-US211-2020-MRNA-1273-P30 1000007
Serious	Yes ● No ○
Death	Yes ○ No ●
Life threatening	Yes ○ No ●
Requires inpatient or prolongation of existing Hospitalization	Yes ● No ○
Persistent or significant disability or incapacity	Yes ○ No ●
Congenital anomaly or birth defect	Yes ○ No ●
Other medically important event	Yes ○ No ●
Investigator's First Name	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/JAN/2021 13:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3912241 (Prod: Synexus - Optimal Research - Austin)

US3912241

Form: Participant Creation

Generated On: 10 Jun 2021 10:20:52

Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'US3912241'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 14:23:29

US3912241
Form: Participant Creation
Generated On: 10 Jun 2021 10:20:52

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 10:20:52
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:30:29

US3912241

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:20:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '12 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 14:23:31

US3912241
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 10:20:52

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Clinic (Clinic)'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:30:29

FDA-CBER-2022-1614-3511267

US3912241
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 10:20:52
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'SCRN'	System	12 Oct 2020 16:30:29

US3912241

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:20:52

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
User entered (b) (6) 1960'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 14:23:33

US3912241
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:20:52

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '59'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:31:19

US3912241
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:20:52
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'YEARS'	System	12 Oct 2020 16:31:19

US3912241
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:20:52
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '59'	System	12 Oct 2020 16:32:19

US3912241

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:20:52

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Male (M)'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:31:19

US3912241
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:20:52
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:31:19

US3912241
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:20:52
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '0'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:31:19

US3912241
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:20:52
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '1'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:31:19

US3912241

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:20:52

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '0'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:31:19

US3912241

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:20:52

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '0'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:31:19

US3912241

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:20:52

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '0'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:31:19

US3912241

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:20:52

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '0'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:31:19

US3912241
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:20:52
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:31:19

US3912241
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:20:52
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '0'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:31:19

US3912241

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:20:52

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '0'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:31:19

US3912241

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:20:52

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '12 Oct 2020'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:32:19

US3912241

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:20:52

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'Oct 2020'	System	12 Oct 2020 16:32:19

US3912241

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:20:52

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '2020'	System	12 Oct 2020 16:32:19

US3912241
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:20:52
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Amendment 4 (4)'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:32:19

US3912241
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:20:52

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:32:19

US3912241

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:20:52

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:32:19

US3912241

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:20:52

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:32:19

US3912241
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:20:52

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:32:19

US3912241

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:20:52

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 14:23:31

US3912241

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:20:52

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '1'	System	12 Oct 2020 16:32:25

US3912241

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:20:52

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:32:25

US3912241

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:20:52

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	30 Oct 2020 19:48:15

US3912241

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:20:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 19:50:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 19:50:10
Data point term sent to Coder	System	30 Oct 2020 19:48:55
User entered 'General body aches'	Mia Rountree (b) (4) (b) (4)	30 Oct 2020 19:48:42

US3912241
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:20:52
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'un UNK 2000'	Mia Rountree (b) (4) (b) (4)	30 Oct 2020 19:48:42

US3912241

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:20:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '0'	Mia Rountree (b) (4) (b) (4)	30 Oct 2020 19:48:42

US3912241

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:20:52

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	30 Oct 2020 19:48:42

US3912241

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:20:52

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	30 Oct 2020 19:48:42

US3912241

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:20:52

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '0'	Mia Rountree (b) (4) (b) (4)	30 Oct 2020 19:48:42

US3912241

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:20:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'Jan 2000'	System	30 Oct 2020 19:48:42

US3912241

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:20:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '2000'	System	30 Oct 2020 19:48:42

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	30 Oct 2020 19:48:42

FDA-CBER-2022-1614-3511304

US3912241

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:20:52

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	30 Oct 2020 19:48:42

US3912241

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:20:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Fruit allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 04:48:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 04:48:35
Data point term sent to Coder	System	30 Oct 2020 19:50:00
User entered 'Allergy to oranges- itchy all over'	Mia Rountree (b) (4) (b) (4)	30 Oct 2020 19:49:13

US3912241

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:20:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	30 Oct 2020 19:49:13

US3912241

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:20:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '1'	Mia Rountree (b) (4) (b) (4)	30 Oct 2020 19:49:13

US3912241

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:20:52

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:49:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 19:49:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	30 Oct 2020 19:49:38
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:49:13
User entered empty.	Mia Rountree (b) (4) (b) (4)	30 Oct 2020 19:49:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	30 Oct 2020 19:49:13

FDA-CBER-2022-1614-3511310

US3912241

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:20:52

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '0'	Mia Rountree (b) (4) (b) (4)	30 Oct 2020 19:49:13

US3912241

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:20:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	30 Oct 2020 19:49:13

US3912241

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:20:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	30 Oct 2020 19:49:13

US3912241

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:20:52

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	30 Oct 2020 19:49:13

US3912241
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:20:52

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	30 Oct 2020 19:49:13

US3912241

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:20:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Pruritus NEC, PT: Pruritus allergic, LLT: Pruritus allergic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 16:28:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 16:28:51
Data point term sent to Coder	System	30 Oct 2020 19:50:08
User entered 'Allergy to tomatoes- itchy all over'	Mia Rountree (b) (4) (b) (4)	30 Oct 2020 19:49:33

US3912241

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:20:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	30 Oct 2020 19:49:33

US3912241

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:20:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '1'	Mia Rountree (b) (4) (b) (4)	30 Oct 2020 19:49:33

US3912241

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:20:52

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	30 Oct 2020 19:49:33

US3912241

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:20:52

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	30 Oct 2020 19:49:33

US3912241

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:20:52

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '0'	Mia Rountree (b) (4) (b) (4)	30 Oct 2020 19:49:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	30 Oct 2020 19:49:33

FDA-CBER-2022-1614-3511322

US3912241

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:20:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	30 Oct 2020 19:49:33

US3912241

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:20:52

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	30 Oct 2020 19:49:33

US3912241

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:20:52

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	30 Oct 2020 19:49:33

US3912241
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:20:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 14:19:36
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'agreed that medication would be expected but subject denies ANY medication' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 22:31:03
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:49:51
User coded data point as SOC: Psychiatric disorders, HLGT: Schizophrenia and other psychotic disorders, HLT: Schizophrenia NEC, PT: Schizophrenia, LLT: Schizophrenic psychoses - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Dec 2020 15:14:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Dec 2020 15:14:59
Data point term sent to Coder	System	05 Dec 2020 18:35:57
User entered 'Schizophrenia Psychotic Disorder'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:35:23

US3912241

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:20:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'un UNK 2006'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:35:23

FDA-CBER-2022-1614-3511327

US3912241

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:20:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '0'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:35:23

US3912241

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:20:52

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:35:23

US3912241

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:20:52

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:35:23

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:20:52

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '0'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:35:23

US3912241

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:20:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'Jan 2006'	System	05 Dec 2020 18:35:23

US3912241

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:20:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '2006'	System	05 Dec 2020 18:35:23

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	05 Dec 2020 18:35:23

US3912241

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:20:52

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	05 Dec 2020 18:35:23

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:48:56

US3912241

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '12 Oct 2020'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:48:56

Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:20:52

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '09:36'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:48:56

US3912241

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '12 Oct 2020 09:36'	System	14 Oct 2020 13:48:56

US3912241
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:20:52

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '68.5' in	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:48:56
DataPoint set to visible.	System	12 Oct 2020 16:32:25

Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:20:52

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '219.0' lb	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:48:56
DataPoint set to visible.	System	12 Oct 2020 16:32:25

US3912241
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:20:52
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '32.88311'	System	14 Oct 2020 13:48:56
DataPoint set to visible.	System	12 Oct 2020 16:32:25

US3912241
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:20:52
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'kg/m2'	System	14 Oct 2020 13:48:56
DataPoint set to visible.	System	12 Oct 2020 16:32:25

US3912241
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:20:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered missing code ND - Not Done.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:48:56

US3912241

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:48:56

US3912241
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:20:52
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:48:56

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered missing code ND - Not Done.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:48:56

US3912241
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:20:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'bpm'	System	14 Oct 2020 13:48:56

US3912241
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:20:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered missing code ND - Not Done.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:48:56

US3912241

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'breaths/min'	System	14 Oct 2020 13:48:56

US3912241
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:20:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered missing code ND - Not Done.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:48:56

US3912241

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'mmHg'	System	14 Oct 2020 13:48:56

US3912241

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered missing code ND - Not Done.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:48:56

US3912241
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:20:52
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'mmHg'	System	14 Oct 2020 13:48:56

Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:20:52

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

FDA-CBER-2022-1614-3511355

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

US3912241
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 10:20:52

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:50:48

US3912241

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:20:52

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '12 Oct 2020'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:50:48

US3912241

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:52

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

US3912241

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:52

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

US3912241

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:52

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:20:52

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

US3912241

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:52

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

US3912241

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:52

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

US3912241

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:52

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:52

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

US3912241

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:52

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

US3912241

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:52

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

US3912241

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:52

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

US3912241

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:52

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'N/A'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

US3912241

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:52

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '0'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

US3912241

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:52

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '0'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

US3912241

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:52

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '0'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

US3912241

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:52

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '0'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

US3912241

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:52

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '0'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

US3912241

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:52

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '1'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

US3912241

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:52

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '0'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

US3912241

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:20:52

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:51:40

US3912241
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 10:20:52
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:30:17

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '12 Oct 2020'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:30:17

FDA-CBER-2022-1614-3511381

US3912241

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:20:52

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Clinic (Clinic)'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:30:17

FDA-CBER-2022-1614-3511382

US3912241
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 10:20:52
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'VISIT1'	System	12 Oct 2020 16:30:17

US3912241

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:20:52

What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '12 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 15:28:24

US3912241

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:20:52

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
User entered '116725'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 15:28:24

US3912241

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:20:52

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Oct 2020 15:28:24

US3912241

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:20:52

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:52:11

US3912241

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:20:52

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:52:11

US3912241

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:20:52

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:52:11

US3912241

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:20:52

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:52:11

US3912241

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:20:52

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:52:11

US3912241

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:20:52

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:52:11
DataPoint set to visible.	System	12 Oct 2020 16:32:19

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:20:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered missing code ND - Not Done.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:20:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered missing code ND - Not Done.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:20:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered missing code ND - Not Done.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

US3912241
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 10:20:52
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered missing code ND - Not Done.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:20:52

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User accepted default value 'Pre-Dose (PREDOSE)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:20:52
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '12 Oct 2020'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:52

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '09:36'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '12 Oct 2020 09:36'	System	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '36.7' C	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Oral (Oral)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:52

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '69'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'bpm'	System	14 Oct 2020 13:54:05

FDA-CBER-2022-1614-3511406

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '15'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'breaths/min'	System	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User closed query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 12:15:41
Query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'Investigator deemed NCS' (Site from DM).	Mia Rountree (b) (4) (b) (4)	26 Oct 2020 20:26:48
User opened query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 17:00:01
User entered '148'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:52

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'mmHg'	System	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User closed query 'Per CDM: Per CCG V2.0 page 50, DBP ≥ 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 11:36:14
Query 'Per CDM: Per CCG V2.0 page 50, DBP ≥ 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'Investigator deemed NCS' (Site from DM).	Mia Rountree (b) (4) (b) (4)	26 Oct 2020 20:26:54
User opened query 'Per CDM: Per CCG V2.0 page 50, DBP ≥ 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 17:00:12
User entered '95'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

FDA-CBER-2022-1614-3511411

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'mmHg'	System	14 Oct 2020 13:54:05

US3912241
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 10:20:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered missing code ND - Not Done.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:20:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered missing code ND - Not Done.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User accepted default value 'Post-Dose (POSTDOSE)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '12 Oct 2020'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '11:53'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '12 Oct 2020 11:53'	System	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '36.9' C	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

FDA-CBER-2022-1614-3511420

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Oral (Oral)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '81'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'bpm'	System	14 Oct 2020 13:54:05

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '16'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'breaths/min'	System	14 Oct 2020 13:54:05

FDA-CBER-2022-1614-3511426

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User closed query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 12:17:30
Query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'Investigator deemed NCS' (Site from DM).	Mia Rountree (b) (4) (b) (4)	26 Oct 2020 20:27:18
User opened query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 17:00:32
User entered '153'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'mmHg'	System	14 Oct 2020 13:54:05

FDA-CBER-2022-1614-3511428

US3912241

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User closed query 'Per CDM: Per CCG V2.0 page 50, DBP ≥ 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 11:36:54
Query 'Per CDM: Per CCG V2.0 page 50, DBP ≥ 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'Investigator deemed NCS' (Site from DM).	Mia Rountree (b) (4) (b) (4)	26 Oct 2020 20:28:48
User opened query 'Per CDM: Per CCG V2.0 page 50, DBP ≥ 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 17:00:42
User entered '97'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'mmHg'	System	14 Oct 2020 13:54:05

FDA-CBER-2022-1614-3511430

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:10

FDA-CBER-2022-1614-3511431

US3912241

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:20:52

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:10

US3912241

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:20:52

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:33:20

US3912241

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:20:52

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:33:20

US3912241

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:20:52

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:33:20

US3912241
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:20:52
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'MRNA-1273 OR PLACEBO'	System	12 Oct 2020 16:33:20

US3912241
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:20:52

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '12 Oct 2020'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:33:20

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '11:17'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:33:20

US3912241
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:20:52
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '12 Oct 2020 11:17'	System	12 Oct 2020 16:33:20

US3912241

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:20:52

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Left Arm (LEFT ARM)'	Tina Rountree (b) (4) (b) (4)	12 Oct 2020 16:33:20

US3912241
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:20:52
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'ONCE'	System	12 Oct 2020 16:33:20

US3912241

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:20:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'INTRAMUSCULAR'	System	12 Oct 2020 16:33:20

US3912241

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:37

US3912241

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '12 Oct 2020'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:37

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '10:38'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:54:37

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '12 Oct 2020 10:38'	System	14 Oct 2020 13:54:37

US3912241

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:20:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '12 Oct 2020'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:55:11

US3912241

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:20:52

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:55:11

US3912241

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:20:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:55:11

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '10:45'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:55:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '12 Oct 2020 10:45'	System	14 Oct 2020 13:55:11

US3912241

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:20:52

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:55:11

US3912241

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:20:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:55:11

US3912241

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:20:52

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:55:11

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:20:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	14 Oct 2020 13:55:11

US3912241

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:20:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:55:16

US3912241
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 10:20:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '1'	System	14 Oct 2020 13:55:16

US3912241
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:20:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T12:01:52', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'b317756c-93b5-4c46-b034-b6292415a730'	System	12 Oct 2020 17:02:44
User entered 'Yes (Y)'	System	12 Oct 2020 17:02:44

US3912241
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:20:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T12:02:06', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'b317756c-93b5-4c46-b034-b6292415a730'	System	12 Oct 2020 17:02:44
User entered '98.5'	System	12 Oct 2020 17:02:44

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:20:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T12:02:12', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'b317756c-93b5-4c46-b034-b6292415a730'	System	12 Oct 2020 17:02:44
User entered 'No (N)'	System	12 Oct 2020 17:02:44

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:20:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T12:02:20', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'b317756c-93b5-4c46-b034-b6292415a730'	System	12 Oct 2020 17:02:44
User entered '12 Oct 2020 12:02'	System	12 Oct 2020 17:02:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '12 Oct 2020 11:37'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:20:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '12 Oct 2020 14:07'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:20:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T20:51:32', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '8fa36942-af31-4123-ac55-267ff72e7abd'	System	13 Oct 2020 01:52:02
User entered 'Yes (Y)'	System	13 Oct 2020 01:52:02

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:20:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T20:51:46', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '8fa36942-af31-4123-ac55-267ff72e7abd'	System	13 Oct 2020 01:52:02
User entered '98.5'	System	13 Oct 2020 01:52:02

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:20:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T20:51:51', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '8fa36942-af31-4123-ac55-267ff72e7abd'	System	13 Oct 2020 01:52:02
User entered 'No (N)'	System	13 Oct 2020 01:52:02

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:20:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T20:51:57', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '8fa36942-af31-4123-ac55-267ff72e7abd'	System	13 Oct 2020 01:52:02
User entered '12 Oct 2020 20:51'	System	13 Oct 2020 01:52:02

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:20:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '12 Oct 2020 15:02'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:20:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 2'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:20:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-13T15:16:30', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '357b2827-f2c0-42f4-afa5-14443e5bf86a'	System	13 Oct 2020 20:17:38
User entered 'Yes (Y)'	System	13 Oct 2020 20:17:38

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:20:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-13T15:16:41', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '357b2827-f2c0-42f4-afa5-14443e5bf86a'	System	13 Oct 2020 20:17:38
User entered '97.7'	System	13 Oct 2020 20:17:38

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:20:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-13T15:16:49', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '357b2827-f2c0-42f4-afa5-14443e5bf86a'	System	13 Oct 2020 20:17:38
User entered 'No (N)'	System	13 Oct 2020 20:17:38

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:20:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-13T15:17:34', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '357b2827-f2c0-42f4-afa5-14443e5bf86a'	System	13 Oct 2020 20:17:38
User entered '13 Oct 2020 15:17'	System	13 Oct 2020 20:17:38

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:20:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 16:33:20

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

FDA-CBER-2022-1614-3511478

US3912241
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 3'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:20:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-14T12:03:11', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '12b51fa3-6091-4fe8-9e7d-6d6733dcd99e'	System	14 Oct 2020 17:03:45
User entered 'Yes (Y)'	System	14 Oct 2020 17:03:45

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:20:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-14T12:03:25', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '12b51fa3-6091-4fe8-9e7d-6d6733dcd99e'	System	14 Oct 2020 17:03:45
User entered '98.0'	System	14 Oct 2020 17:03:45

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:20:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-14T12:03:35', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '12b51fa3-6091-4fe8-9e7d-6d6733dcd99e'	System	14 Oct 2020 17:03:45
User entered 'No (N)'	System	14 Oct 2020 17:03:45

US3912241
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:20:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-14T12:03:41', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '12b51fa3-6091-4fe8-9e7d-6d6733dcd99e'	System	14 Oct 2020 17:03:45
User entered '14 Oct 2020 12:03'	System	14 Oct 2020 17:03:45

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:20:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 16:33:20

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 4'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:20:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-15T13:46:41', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'ead6ad2c-aa0b-40d3-98fb-fc9b20b212c9'	System	15 Oct 2020 18:48:08
User entered 'Yes (Y)'	System	15 Oct 2020 18:48:08

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:20:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-15T13:46:50', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'ead6ad2c-aa0b-40d3-98fb-fc9b20b212c9'	System	15 Oct 2020 18:48:08
User entered '97.4'	System	15 Oct 2020 18:48:08

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:20:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-15T13:47:12', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'ead6ad2c-aa0b-40d3-98fb-fc9b20b212c9'	System	15 Oct 2020 18:48:08
User entered 'No (N)'	System	15 Oct 2020 18:48:08

FDA-CBER-2022-1614-3511489

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:20:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-15T13:48:01', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'ead6ad2c-aa0b-40d3-98fb-fc9b20b212c9'	System	15 Oct 2020 18:48:08
User entered '15 Oct 2020 13:48'	System	15 Oct 2020 18:48:08

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 16:33:20

FDA-CBER-2022-1614-3511491

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:20:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 5'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:20:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-16T16:39:29', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '106b8d13-38d3-4da1-8fa9-dcd8772f29c4'	System	16 Oct 2020 21:39:59
User entered 'Yes (Y)'	System	16 Oct 2020 21:39:59

FDA-CBER-2022-1614-3511494

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:20:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-16T16:39:37', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '106b8d13-38d3-4da1-8fa9-dcd8772f29c4'	System	16 Oct 2020 21:39:59
User entered '98.0'	System	16 Oct 2020 21:39:59

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:20:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-16T16:39:42', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '106b8d13-38d3-4da1-8fa9-dcd8772f29c4'	System	16 Oct 2020 21:39:59
User entered 'No (N)'	System	16 Oct 2020 21:39:59

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:20:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-16T16:39:55', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '106b8d13-38d3-4da1-8fa9-dcd8772f29c4'	System	16 Oct 2020 21:39:59
User entered '16 Oct 2020 16:39'	System	16 Oct 2020 21:39:59

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:20:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:20:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:20:52

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 6'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:20:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-17T22:07:56', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '6b2e8838-03b3-4cbf-838f-2e37796ee70b'	System	18 Oct 2020 03:09:49
User entered 'Yes (Y)'	System	18 Oct 2020 03:09:49

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:20:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-17T22:09:39', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '6b2e8838-03b3-4cbf-838f-2e37796ee70b'	System	18 Oct 2020 03:09:49
User entered '96.5'	System	18 Oct 2020 03:09:49

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:20:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-17T22:09:43', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '6b2e8838-03b3-4cbf-838f-2e37796ee70b'	System	18 Oct 2020 03:09:49
User entered 'No (N)'	System	18 Oct 2020 03:09:49

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:20:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-17T22:09:47', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '6b2e8838-03b3-4cbf-838f-2e37796ee70b'	System	18 Oct 2020 03:09:49
User entered '17 Oct 2020 22:09'	System	18 Oct 2020 03:09:49

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:20:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:20:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 7'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:20:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-19T06:36:23', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'a4a81252-3c93-4d34-a89b-c7a735309304'	System	19 Oct 2020 11:36:43
User entered 'Yes (Y)'	System	19 Oct 2020 11:36:43

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:20:52

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-19T06:36:31', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'a4a81252-3c93-4d34-a89b-c7a735309304'	System	19 Oct 2020 11:36:43
User entered '98.0'	System	19 Oct 2020 11:36:43

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:20:52

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-19T06:36:38', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'a4a81252-3c93-4d34-a89b-c7a735309304'	System	19 Oct 2020 11:36:43
User entered 'No (N)'	System	19 Oct 2020 11:36:43

US3912241
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:20:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-19T06:36:41', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'a4a81252-3c93-4d34-a89b-c7a735309304'	System	19 Oct 2020 11:36:43
User entered '19 Oct 2020 06:36'	System	19 Oct 2020 11:36:43

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 16:33:20

FDA-CBER-2022-1614-3511512

US3912241

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:20:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:20:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T12:02:34', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '5b412a37-8964-4b3b-8192-d2d52a315a7e'	System	12 Oct 2020 17:03:05
User entered 'None (1)'	System	12 Oct 2020 17:03:05

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:20:52

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T12:02:39', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '5b412a37-8964-4b3b-8192-d2d52a315a7e'	System	12 Oct 2020 17:03:05
User entered 'No (N)'	System	12 Oct 2020 17:03:05

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:20:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T12:02:41', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '5b412a37-8964-4b3b-8192-d2d52a315a7e'	System	12 Oct 2020 17:03:05
User entered 'No (N)'	System	12 Oct 2020 17:03:05

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:20:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T12:02:45', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '5b412a37-8964-4b3b-8192-d2d52a315a7e'	System	12 Oct 2020 17:03:05
User entered 'None (1)'	System	12 Oct 2020 17:03:05

US3912241
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:20:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T12:02:51', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '5b412a37-8964-4b3b-8192-d2d52a315a7e'	System	12 Oct 2020 17:03:05
User entered '12 Oct 2020 12:02'	System	12 Oct 2020 17:03:05

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:20:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '12 Oct 2020 11:37'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:20:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '12 Oct 2020 14:07'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:20:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T20:52:02', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '1316f3ed-763d-44d9-8586-bdc572114cb8'	System	13 Oct 2020 01:52:21
User entered 'None (1)'	System	13 Oct 2020 01:52:21

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:20:52

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T20:52:06', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '1316f3ed-763d-44d9-8586-bdc572114cb8'	System	13 Oct 2020 01:52:21
User entered 'No (N)'	System	13 Oct 2020 01:52:21

FDA-CBER-2022-1614-3511524

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:20:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T20:52:10', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '1316f3ed-763d-44d9-8586-bdc572114cb8'	System	13 Oct 2020 01:52:21
User entered 'No (N)'	System	13 Oct 2020 01:52:21

FDA-CBER-2022-1614-3511525

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:20:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T20:52:16', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '1316f3ed-763d-44d9-8586-bdc572114cb8'	System	13 Oct 2020 01:52:21
User entered 'None (1)'	System	13 Oct 2020 01:52:21

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:20:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T20:52:19', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '1316f3ed-763d-44d9-8586-bdc572114cb8'	System	13 Oct 2020 01:52:21
User entered '12 Oct 2020 20:52'	System	13 Oct 2020 01:52:21

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:20:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '12 Oct 2020 15:02'	System	12 Oct 2020 16:33:20

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

FDA-CBER-2022-1614-3511529

US3912241
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 2'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:20:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-13T15:14:46', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '4b872c41-84ea-446e-9bdc-30264a8076cc'	System	13 Oct 2020 20:15:08
User entered 'Does not interfere with activity (2)'	System	13 Oct 2020 20:15:08

US3912241
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:20:52

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-13T15:14:51', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '4b872c41-84ea-446e-9bdc-30264a8076cc'	System	13 Oct 2020 20:15:08
User entered 'No (N)'	System	13 Oct 2020 20:15:08

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:20:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-13T15:14:55', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '4b872c41-84ea-446e-9bdc-30264a8076cc'	System	13 Oct 2020 20:15:08
User entered 'No (N)'	System	13 Oct 2020 20:15:08

FDA-CBER-2022-1614-3511533

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:20:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-13T15:14:59', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '4b872c41-84ea-446e-9bdc-30264a8076cc'	System	13 Oct 2020 20:15:08
User entered 'None (1)'	System	13 Oct 2020 20:15:08

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:20:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-13T15:15:04', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '4b872c41-84ea-446e-9bdc-30264a8076cc'	System	13 Oct 2020 20:15:08
User entered '13 Oct 2020 15:15'	System	13 Oct 2020 20:15:08

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:20:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 16:33:20

Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:20:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 3'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:20:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-14T12:01:32', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '7c4fc7d4-3c3f-441a-ae06-4e3080b3c165'	System	14 Oct 2020 17:02:45
User entered 'None (1)'	System	14 Oct 2020 17:02:45

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:20:52

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-14T12:02:00', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '7c4fc7d4-3c3f-441a-ae06-4e3080b3c165'	System	14 Oct 2020 17:02:45
User entered 'No (N)'	System	14 Oct 2020 17:02:45

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:20:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-14T12:02:04', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '7c4fc7d4-3c3f-441a-ae06-4e3080b3c165'	System	14 Oct 2020 17:02:45
User entered 'No (N)'	System	14 Oct 2020 17:02:45

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:20:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-14T12:02:07', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '7c4fc7d4-3c3f-441a-ae06-4e3080b3c165'	System	14 Oct 2020 17:02:45
User entered 'None (1)'	System	14 Oct 2020 17:02:45

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:20:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-14T12:02:11', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '7c4fc7d4-3c3f-441a-ae06-4e3080b3c165'	System	14 Oct 2020 17:02:45
User entered '14 Oct 2020 12:02'	System	14 Oct 2020 17:02:45

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:20:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 4'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:20:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-15T13:48:07', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'f05490ff-67c5-49f7-bae2-22ab5f013af5'	System	15 Oct 2020 18:49:58
User entered 'None (1)'	System	15 Oct 2020 18:49:58

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:20:52

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-15T13:48:24', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'f05490ff-67c5-49f7-bae2-22ab5f013af5'	System	15 Oct 2020 18:49:58
User entered 'No (N)'	System	15 Oct 2020 18:49:58

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:20:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-15T13:48:34', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'f05490ff-67c5-49f7-bae2-22ab5f013af5'	System	15 Oct 2020 18:49:58
User entered 'No (N)'	System	15 Oct 2020 18:49:58

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:20:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-15T13:49:50', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'f05490ff-67c5-49f7-bae2-22ab5f013af5'	System	15 Oct 2020 18:49:58
User entered 'None (1)'	System	15 Oct 2020 18:49:58

US3912241
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:20:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-15T13:49:54', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'f05490ff-67c5-49f7-bae2-22ab5f013af5'	System	15 Oct 2020 18:49:58
User entered '15 Oct 2020 13:49'	System	15 Oct 2020 18:49:58

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:20:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:20:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 5'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:20:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-16T16:40:03', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '97df5db2-b9d1-459c-a9ca-696b686d3474'	System	16 Oct 2020 21:40:20
User entered 'None (1)'	System	16 Oct 2020 21:40:20

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:20:52

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-16T16:40:07', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '97df5db2-b9d1-459c-a9ca-696b686d3474'	System	16 Oct 2020 21:40:20
User entered 'No (N)'	System	16 Oct 2020 21:40:20

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:20:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-16T16:40:10', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '97df5db2-b9d1-459c-a9ca-696b686d3474'	System	16 Oct 2020 21:40:20
User entered 'No (N)'	System	16 Oct 2020 21:40:20

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:20:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-16T16:40:13', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '97df5db2-b9d1-459c-a9ca-696b686d3474'	System	16 Oct 2020 21:40:20
User entered 'None (1)'	System	16 Oct 2020 21:40:20

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:20:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-16T16:40:16', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '97df5db2-b9d1-459c-a9ca-696b686d3474'	System	16 Oct 2020 21:40:20
User entered '16 Oct 2020 16:40'	System	16 Oct 2020 21:40:20

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:20:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:20:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 6'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:20:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-17T22:09:53', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '76177983-d277-4924-9b43-f5995f084fe3'	System	18 Oct 2020 03:10:09
User entered 'None (1)'	System	18 Oct 2020 03:10:09

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:20:52

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-17T22:09:56', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '76177983-d277-4924-9b43-f5995f084fe3'	System	18 Oct 2020 03:10:09
User entered 'No (N)'	System	18 Oct 2020 03:10:09

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:20:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-17T22:09:58', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '76177983-d277-4924-9b43-f5995f084fe3'	System	18 Oct 2020 03:10:09
User entered 'No (N)'	System	18 Oct 2020 03:10:09

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:20:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-17T22:10:02', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '76177983-d277-4924-9b43-f5995f084fe3'	System	18 Oct 2020 03:10:09
User entered 'None (1)'	System	18 Oct 2020 03:10:09

US3912241
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:20:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-17T22:10:07', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '76177983-d277-4924-9b43-f5995f084fe3'	System	18 Oct 2020 03:10:09
User entered '17 Oct 2020 22:10'	System	18 Oct 2020 03:10:09

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:20:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:20:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 7'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:20:52

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-19T06:36:46', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '6aea1723-f328-4489-bbf5-de6572604473'	System	19 Oct 2020 11:37:01
User entered 'None (1)'	System	19 Oct 2020 11:37:01

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:20:52

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-19T06:36:49', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '6aea1723-f328-4489-bbf5-de6572604473'	System	19 Oct 2020 11:37:01
User entered 'No (N)'	System	19 Oct 2020 11:37:01

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:20:52

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-19T06:36:52', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '6aea1723-f328-4489-bbf5-de6572604473'	System	19 Oct 2020 11:37:01
User entered 'No (N)'	System	19 Oct 2020 11:37:01

FDA-CBER-2022-1614-3511573

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:20:52

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-19T06:36:56', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '6aea1723-f328-4489-bbf5-de6572604473'	System	19 Oct 2020 11:37:01
User entered 'None (1)'	System	19 Oct 2020 11:37:01

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:20:52

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-19T06:36:58', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '6aea1723-f328-4489-bbf5-de6572604473'	System	19 Oct 2020 11:37:01
User entered '19 Oct 2020 06:36'	System	19 Oct 2020 11:37:01

PRODUCTION RELEASE (v12.003
EAB) (1725)

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:20:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:20:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:20:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T12:03:01', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '1a5c4ab1-81c4-43db-bd0c-5274aadb52b8'	System	12 Oct 2020 17:03:28
User entered 'None (0)'	System	12 Oct 2020 17:03:28

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:20:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T12:03:04', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '1a5c4ab1-81c4-43db-bd0c-5274aadb52b8'	System	12 Oct 2020 17:03:28
User entered 'None (0)'	System	12 Oct 2020 17:03:28

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:20:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T12:03:07', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '1a5c4ab1-81c4-43db-bd0c-5274aadb52b8'	System	12 Oct 2020 17:03:28
User entered 'None (0)'	System	12 Oct 2020 17:03:28

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:20:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T12:03:12', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '1a5c4ab1-81c4-43db-bd0c-5274aadb52b8'	System	12 Oct 2020 17:03:28
User entered 'None (0)'	System	12 Oct 2020 17:03:28

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:20:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T12:03:15', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '1a5c4ab1-81c4-43db-bd0c-5274aadb52b8'	System	12 Oct 2020 17:03:28
User entered 'None (0)'	System	12 Oct 2020 17:03:28

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:20:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T12:03:17', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '1a5c4ab1-81c4-43db-bd0c-5274aadb52b8'	System	12 Oct 2020 17:03:28
User entered 'None (0)'	System	12 Oct 2020 17:03:28

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:20:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T12:03:21', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '1a5c4ab1-81c4-43db-bd0c-5274aadb52b8'	System	12 Oct 2020 17:03:28
User entered 'No (N)'	System	12 Oct 2020 17:03:28

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:20:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T12:03:26', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '1a5c4ab1-81c4-43db-bd0c-5274aadb52b8'	System	12 Oct 2020 17:03:28
User entered '12 Oct 2020 12:03'	System	12 Oct 2020 17:03:28

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '12 Oct 2020 11:37'	System	12 Oct 2020 16:33:20

FDA-CBER-2022-1614-3511587

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:20:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '12 Oct 2020 14:07'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:20:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T20:52:29', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '7b891bd5-636b-479b-b2ea-71420682b88a'	System	13 Oct 2020 01:53:08
User entered 'None (0)'	System	13 Oct 2020 01:53:08

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:20:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T20:52:36', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '7b891bd5-636b-479b-b2ea-71420682b88a'	System	13 Oct 2020 01:53:08
User entered 'None (0)'	System	13 Oct 2020 01:53:08

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:20:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T20:52:41', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '7b891bd5-636b-479b-b2ea-71420682b88a'	System	13 Oct 2020 01:53:08
User entered 'None (0)'	System	13 Oct 2020 01:53:08

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:20:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T20:52:46', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '7b891bd5-636b-479b-b2ea-71420682b88a'	System	13 Oct 2020 01:53:08
User entered 'None (0)'	System	13 Oct 2020 01:53:08

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:20:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T20:52:52', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '7b891bd5-636b-479b-b2ea-71420682b88a'	System	13 Oct 2020 01:53:08
User entered 'None (0)'	System	13 Oct 2020 01:53:08

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:20:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T20:52:56', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '7b891bd5-636b-479b-b2ea-71420682b88a'	System	13 Oct 2020 01:53:08
User entered 'None (0)'	System	13 Oct 2020 01:53:08

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:20:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T20:53:01', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '7b891bd5-636b-479b-b2ea-71420682b88a'	System	13 Oct 2020 01:53:08
User entered 'No (N)'	System	13 Oct 2020 01:53:08

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:20:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-12T20:53:07', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '7b891bd5-636b-479b-b2ea-71420682b88a'	System	13 Oct 2020 01:53:08
User entered '12 Oct 2020 20:53'	System	13 Oct 2020 01:53:08

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:20:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '12 Oct 2020 15:02'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:20:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 2'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:20:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-13T15:15:15', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '4cb2c230-93bc-4775-8d94-2a115796e327'	System	13 Oct 2020 20:16:14
User entered 'No interference with activity (1)'	System	13 Oct 2020 20:16:14

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:20:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-13T15:15:22', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '4cb2c230-93bc-4775-8d94-2a115796e327'	System	13 Oct 2020 20:16:14
User entered 'No interference with activity (1)'	System	13 Oct 2020 20:16:14

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:20:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-13T15:15:26', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '4cb2c230-93bc-4775-8d94-2a115796e327'	System	13 Oct 2020 20:16:14
User entered 'None (0)'	System	13 Oct 2020 20:16:14

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:20:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-13T15:15:30', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '4cb2c230-93bc-4775-8d94-2a115796e327'	System	13 Oct 2020 20:16:14
User entered 'No interference with activity (1)'	System	13 Oct 2020 20:16:14

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:20:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-13T15:15:38', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '4cb2c230-93bc-4775-8d94-2a115796e327'	System	13 Oct 2020 20:16:14
User entered 'None (0)'	System	13 Oct 2020 20:16:14

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:20:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-13T15:15:55', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '4cb2c230-93bc-4775-8d94-2a115796e327'	System	13 Oct 2020 20:16:14
User entered 'None (0)'	System	13 Oct 2020 20:16:14

FDA-CBER-2022-1614-3511606

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:20:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-13T15:16:01', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '4cb2c230-93bc-4775-8d94-2a115796e327'	System	13 Oct 2020 20:16:14
User entered 'No (N)'	System	13 Oct 2020 20:16:14

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:20:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-13T15:16:10', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '4cb2c230-93bc-4775-8d94-2a115796e327'	System	13 Oct 2020 20:16:14
User entered '13 Oct 2020 15:16'	System	13 Oct 2020 20:16:14

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:20:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 16:33:20

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

FDA-CBER-2022-1614-3511610

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 3'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:20:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-14T12:02:22', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '169c3de5-3e50-4a4c-9813-4f7589e9e2f1'	System	14 Oct 2020 17:03:05
User entered 'None (0)'	System	14 Oct 2020 17:03:05

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:20:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-14T12:02:25', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '169c3de5-3e50-4a4c-9813-4f7589e9e2f1'	System	14 Oct 2020 17:03:05
User entered 'None (0)'	System	14 Oct 2020 17:03:05

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:20:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-14T12:02:28', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '169c3de5-3e50-4a4c-9813-4f7589e9e2f1'	System	14 Oct 2020 17:03:05
User entered 'None (0)'	System	14 Oct 2020 17:03:05

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:20:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-14T12:02:34', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '169c3de5-3e50-4a4c-9813-4f7589e9e2f1'	System	14 Oct 2020 17:03:05
User entered 'None (0)'	System	14 Oct 2020 17:03:05

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:20:52

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-14T12:02:44', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '169c3de5-3e50-4a4c-9813-4f7589e9e2f1'	System	14 Oct 2020 17:03:05
User entered 'None (0)'	System	14 Oct 2020 17:03:05

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:20:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-14T12:02:49', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '169c3de5-3e50-4a4c-9813-4f7589e9e2f1'	System	14 Oct 2020 17:03:05
User entered 'None (0)'	System	14 Oct 2020 17:03:05

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:20:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-14T12:02:53', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '169c3de5-3e50-4a4c-9813-4f7589e9e2f1'	System	14 Oct 2020 17:03:05
User entered 'No (N)'	System	14 Oct 2020 17:03:05

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:20:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-14T12:02:59', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '169c3de5-3e50-4a4c-9813-4f7589e9e2f1'	System	14 Oct 2020 17:03:05
User entered '14 Oct 2020 12:02'	System	14 Oct 2020 17:03:05

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:20:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 4'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:20:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57

FDA-CBER-2022-1614-3511624

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:20:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:20:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:20:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57

Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:20:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 16:33:20

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 5'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:20:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-16T16:40:23', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '3c514fe5-9efe-47fa-831d-04ea8a5f4141'	System	16 Oct 2020 21:40:49
User entered 'None (0)'	System	16 Oct 2020 21:40:49

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:20:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-16T16:40:26', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '3c514fe5-9efe-47fa-831d-04ea8a5f4141'	System	16 Oct 2020 21:40:49
User entered 'None (0)'	System	16 Oct 2020 21:40:49

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:20:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-16T16:40:29', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '3c514fe5-9efe-47fa-831d-04ea8a5f4141'	System	16 Oct 2020 21:40:49
User entered 'None (0)'	System	16 Oct 2020 21:40:49

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:20:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-16T16:40:32', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '3c514fe5-9efe-47fa-831d-04ea8a5f4141'	System	16 Oct 2020 21:40:49
User entered 'None (0)'	System	16 Oct 2020 21:40:49

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:20:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-16T16:40:35', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '3c514fe5-9efe-47fa-831d-04ea8a5f4141'	System	16 Oct 2020 21:40:49
User entered 'None (0)'	System	16 Oct 2020 21:40:49

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:20:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-16T16:40:38', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '3c514fe5-9efe-47fa-831d-04ea8a5f4141'	System	16 Oct 2020 21:40:49
User entered 'None (0)'	System	16 Oct 2020 21:40:49

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:20:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-16T16:40:42', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '3c514fe5-9efe-47fa-831d-04ea8a5f4141'	System	16 Oct 2020 21:40:49
User entered 'No (N)'	System	16 Oct 2020 21:40:49

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:20:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-16T16:40:45', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '3c514fe5-9efe-47fa-831d-04ea8a5f4141'	System	16 Oct 2020 21:40:49
User entered '16 Oct 2020 16:40'	System	16 Oct 2020 21:40:49

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:20:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:20:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 6'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:20:52

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-17T22:10:17', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '6dc04094-7e42-471f-8204-982ead2c92c7'	System	18 Oct 2020 03:11:10
User entered 'None (0)'	System	18 Oct 2020 03:11:10

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:20:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-17T22:10:31', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '6dc04094-7e42-471f-8204-982ead2c92c7'	System	18 Oct 2020 03:11:10
User entered 'No interference with activity (1)'	System	18 Oct 2020 03:11:10

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:20:52

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-17T22:10:48', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '6dc04094-7e42-471f-8204-982ead2c92c7'	System	18 Oct 2020 03:11:10
User entered 'None (0)'	System	18 Oct 2020 03:11:10

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:20:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-17T22:10:52', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '6dc04094-7e42-471f-8204-982ead2c92c7'	System	18 Oct 2020 03:11:10
User entered 'None (0)'	System	18 Oct 2020 03:11:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-17T22:10:56', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '6dc04094-7e42-471f-8204-982ead2c92c7'	System	18 Oct 2020 03:11:10
User entered 'None (0)'	System	18 Oct 2020 03:11:10

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:20:52

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-17T22:11:01', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '6dc04094-7e42-471f-8204-982ead2c92c7'	System	18 Oct 2020 03:11:10
User entered 'None (0)'	System	18 Oct 2020 03:11:10

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:20:52
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-17T22:11:05', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '6dc04094-7e42-471f-8204-982ead2c92c7'	System	18 Oct 2020 03:11:10
User entered 'No (N)'	System	18 Oct 2020 03:11:10

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:20:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-17T22:11:08', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '6dc04094-7e42-471f-8204-982ead2c92c7'	System	18 Oct 2020 03:11:10
User entered '17 Oct 2020 22:11'	System	18 Oct 2020 03:11:10

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:20:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:20:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
Data entry locked.	System	12 Oct 2020 16:33:20
User entered 'Day 7'	System	12 Oct 2020 16:33:20

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:20:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-19T06:37:03', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '693ee7ea-7336-4b19-961f-9eb156e94105'	System	19 Oct 2020 11:37:24
User entered 'None (0)'	System	19 Oct 2020 11:37:24

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:20:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-19T06:37:05', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '693ee7ea-7336-4b19-961f-9eb156e94105'	System	19 Oct 2020 11:37:24
User entered 'None (0)'	System	19 Oct 2020 11:37:24

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:20:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-19T06:37:08', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '693ee7ea-7336-4b19-961f-9eb156e94105'	System	19 Oct 2020 11:37:24
User entered 'None (0)'	System	19 Oct 2020 11:37:24

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:20:52

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-19T06:37:10', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '693ee7ea-7336-4b19-961f-9eb156e94105'	System	19 Oct 2020 11:37:24
User entered 'None (0)'	System	19 Oct 2020 11:37:24

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:20:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-19T06:37:12', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '693ee7ea-7336-4b19-961f-9eb156e94105'	System	19 Oct 2020 11:37:24
User entered 'None (0)'	System	19 Oct 2020 11:37:24

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:20:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-19T06:37:15', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '693ee7ea-7336-4b19-961f-9eb156e94105'	System	19 Oct 2020 11:37:24
User entered 'None (0)'	System	19 Oct 2020 11:37:24

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:20:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-19T06:37:20', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '693ee7ea-7336-4b19-961f-9eb156e94105'	System	19 Oct 2020 11:37:24
User entered 'No (N)'	System	19 Oct 2020 11:37:24

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:20:52

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F87133B3-F3B7-4112-B91E-BF5D3A1EE9E9)', Time: '2020-10-19T06:37:22', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '693ee7ea-7336-4b19-961f-9eb156e94105'	System	19 Oct 2020 11:37:24
User entered '19 Oct 2020 06:37'	System	19 Oct 2020 11:37:24

US3912241
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:20:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 16:33:20

US3912241

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:20:52

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:56:57
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 16:33:20

US3912241

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	19 Oct 2020 18:57:11

US3912241
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:20:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
	(b) (4)	
User entered '19 Oct 2020'	Amy Collins (b) (4)	19 Oct 2020 18:57:11
	(b) (4)	

US3912241

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Contact Made (CONTACT MADE)'	Amy Collins (b) (4) (b) (4)	19 Oct 2020 18:57:11

US3912241

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Amy Collins (b) (4) (b) (4)	19 Oct 2020 18:57:11

US3912241

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	19 Oct 2020 18:57:19

US3912241

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '1'	System	19 Oct 2020 18:57:19

US3912241

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	26 Oct 2020 16:26:01

US3912241

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '26 Oct 2020'	Mia Rountree (b) (4) (b) (4)	26 Oct 2020 16:26:01

US3912241
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:20:52
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Contact Made (CONTACT MADE)'	Mia Rountree (b) (4) (b) (4)	26 Oct 2020 16:26:01

US3912241

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	26 Oct 2020 16:26:01

US3912241

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	26 Oct 2020 16:26:06

US3912241
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:20:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '1'	System	26 Oct 2020 16:26:06

US3912241

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	02 Nov 2020 20:25:48

US3912241

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '2 Nov 2020'	Mia Rountree (b) (4) (b) (4)	02 Nov 2020 20:25:48

US3912241

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Contact Made (CONTACT MADE)'	Mia Rountree (b) (4) (b) (4)	02 Nov 2020 20:25:48

FDA-CBER-2022-1614-3511680

US3912241

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	02 Nov 2020 20:25:48

US3912241

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	02 Nov 2020 20:25:54

US3912241

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '1'	System	02 Nov 2020 20:25:54

US3912241
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:20:52
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 09NOV2020 is reported under Visit 2 Day 29 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 12:17:24
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 09NOV2020 for the Visit 2 Day 29 Visit, however, there is no data recorded for the Visit 2 Day 29 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 13:51:39
Query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 09NOV2020 for the Visit 2 Day 29 Visit, however, there is no data recorded for the Visit 2 Day 29 Visit. Please clarify and update as appropriate.' answered with 'visit 2 completed' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	20 Nov 2020 19:28:42
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 09NOV2020 is reported under Visit 2 Day 29 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Day 29 visit completed' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	20 Nov 2020 19:28:31
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 09NOV2020 for the Visit 2 Day 29 Visit, however, there is no data recorded for the Visit 2 Day 29 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:08:40

US3912241
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:20:52

Was this visit performed?

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 09NOV2020 is reported under Visit 2 Day 29 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:21:48
Query 'US3912241 ' canceled (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:21:44
User opened query 'US3912241 ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:21:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 17:32:07

US3912241

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:20:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
User entered '09 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:32:07

US3912241

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:20:52

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Nov 2020 17:32:07

US3912241
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:20:52
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User entered 'VISIT2'	System	16 Nov 2020 17:32:07

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User accepted default value 'Pre-Dose (PREDOSE)'	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 00:59:20

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:20:52
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 00:59:20

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '9 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 00:59:20

US3912241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:52

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '09:44'	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 00:59:20

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User entered '9 Nov 2020 09:44'	System	06 Feb 2021 00:59:20

FDA-CBER-2022-1614-3511693

US3912241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '98.9' F	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 00:59:20

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Oral (Oral)'	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 00:59:20

US3912241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:52

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 00:59:20

US3912241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '86'	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 00:59:20

US3912241
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:20:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User entered 'bpm'	System	06 Feb 2021 00:59:20

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '14'	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 00:59:20

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User entered 'breaths/min'	System	06 Feb 2021 00:59:20

FDA-CBER-2022-1614-3511700

US3912241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '129'	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 00:59:20

FDA-CBER-2022-1614-3511701

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User entered 'mmHg'	System	06 Feb 2021 00:59:20

FDA-CBER-2022-1614-3511702

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '82'	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 00:59:20

FDA-CBER-2022-1614-3511703

US3912241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:20:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User entered 'mmHg'	System	06 Feb 2021 00:59:20

US3912241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User accepted default value 'Post-Dose (POSTDOSE)'	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 01:00:25

US3912241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 01:00:25

US3912241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 01:00:25

US3912241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 01:00:25

US3912241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User entered empty.	System	06 Feb 2021 01:00:25

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 01:00:25

FDA-CBER-2022-1614-3511710

US3912241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 01:00:25

FDA-CBER-2022-1614-3511711

US3912241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 01:00:25

US3912241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 01:00:25

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User entered empty.	System	06 Feb 2021 01:00:25

FDA-CBER-2022-1614-3511714

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 01:00:25

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User entered empty.	System	06 Feb 2021 01:00:25

US3912241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 01:00:25

US3912241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User entered empty.	System	06 Feb 2021 01:00:25

US3912241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 01:00:25

US3912241

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:20:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User entered empty.	System	06 Feb 2021 01:00:25

US3912241

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:20:52

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	20 Nov 2020 19:24:22

US3912241

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:20:52

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '9 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	20 Nov 2020 19:24:22

US3912241

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:20:52

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:31:49

US3912241
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:20:52

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
User closed query 'PER CDM: Please complete the dose discontinuation and end of study discontinuation forms if appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 04:28:28
Query 'PER CDM: Please complete the dose discontinuation and end of study discontinuation forms if appropriate. Thank you.' answered with 'dose discontinuation completed' (Site from DM).	Sandra Clancy (b) (4)	20 Nov 2020 19:22:51
User opened query 'PER CDM: Please complete the dose discontinuation and end of study discontinuation forms if appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 08:50:55
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4), (b) (6)	16 Nov 2020 17:31:49

US3912241

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:20:52

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:31:49

US3912241
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:20:52
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	16 Nov 2020 17:31:49

US3912241

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:20:52

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 17:31:49

Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:20:52

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 17:31:49

US3912241

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:20:52

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	16 Nov 2020 17:31:49

US3912241

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:20:52

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:31:49

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	16 Nov 2020 17:31:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	16 Nov 2020 17:31:49

US3912241

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	20 Nov 2020 19:24:59

US3912241

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '9 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	20 Nov 2020 19:24:59

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '10:50'	Sandra Clancy (b) (4) (b) (4)	20 Nov 2020 19:24:59

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User entered '9 Nov 2020 10:50'	System	20 Nov 2020 19:24:59

US3912241

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:20:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	20 Nov 2020 19:25:53
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	20 Nov 2020 19:25:53
User entered '9 Nov 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	20 Nov 2020 19:25:53
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	20 Nov 2020 19:25:44
User entered empty.	Sandra Clancy (b) (4) (b) (4)	20 Nov 2020 19:25:28

US3912241

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:20:52

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sandra Clancy (b) (4) (b) (4)	20 Nov 2020 19:25:28

US3912241

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:20:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	20 Nov 2020 19:25:28

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '10:55'	Sandra Clancy (b) (4) (b) (4)	20 Nov 2020 19:25:28

FDA-CBER-2022-1614-3511740

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '9 Nov 2020 10:55'	System	20 Nov 2020 19:25:53
User entered empty.	System	20 Nov 2020 19:25:28

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sandra Clancy (b) (4) (b) (4)	20 Nov 2020 19:25:44

US3912241

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:20:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	20 Nov 2020 19:25:44

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Sandra Clancy (b) (4) (b) (4)	20 Nov 2020 19:25:44

US3912241

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:20:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	20 Nov 2020 19:25:44

US3912241
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:20:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:21:27

US3912241
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:20:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '1'	System	16 Nov 2020 17:21:27

US3912241

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 17:33:25

US3912241

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
User entered '16 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 17:33:25

US3912241

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Nov 2020 17:33:25

US3912241

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:33:25

US3912241

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:33:30

US3912241
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:20:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '1'	System	16 Nov 2020 17:33:30

US3912241
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:20:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:43:35

FDA-CBER-2022-1614-3511754

US3912241

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '23 Nov 2020'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:43:35

US3912241

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Contact Made (CONTACT MADE)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:43:35

US3912241

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:43:35

US3912241

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:43:40

US3912241
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:20:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '1'	System	07 Dec 2020 17:43:40

US3912241
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:20:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:44:02

US3912241

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '30 Nov 2020'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:44:02

US3912241

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Contact Made (CONTACT MADE)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:44:02

US3912241

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:44:02

US3912241

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:44:07

US3912241
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:20:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '1'	System	07 Dec 2020 17:44:07

US3912241

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:20:52

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:44:53

US3912241
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:20:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '04 Dec 2020'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:44:53

US3912241

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:20:52

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Clinic (Clinic)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:44:53

US3912241
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:20:52
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User entered 'VISIT3'	System	07 Dec 2020 17:44:53

US3912241

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:47:34

US3912241

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '04 Dec 2020'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:47:34

US3912241

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '13:23'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:47:34

US3912241

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User entered '04 Dec 2020 13:23'	System	07 Dec 2020 17:47:34

US3912241

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '36.9' C	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:47:34

US3912241

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Oral (Oral)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:47:34

US3912241

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:47:34

US3912241

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '78'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:47:34

US3912241
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:20:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User entered 'bpm'	System	07 Dec 2020 17:47:34

US3912241

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User closed query 'Per CDM: Per CCG V2.0 page 53, Respiratory Rate: ≥ 17 breaths per minute (breaths/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 10:28:56
Query 'Per CDM: Per CCG V2.0 page 53, Respiratory Rate: ≥ 17 breaths per minute (breaths/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' answered with 'Investigator deemed NCS' (Site from DM).	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 16:26:52
User opened query 'Per CDM: Per CCG V2.0 page 53, Respiratory Rate: ≥ 17 breaths per minute (breaths/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 12:08:46
User entered '20'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:47:34

US3912241

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User entered 'breaths/min'	System	07 Dec 2020 17:47:34

US3912241

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User closed query 'Per CDM: Per CCG V2.0 page 53, SBP ≤ 89 or ≥141 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 11:02:37
Query 'Per CDM: Per CCG V2.0 page 53, SBP ≤ 89 or ≥141 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' answered with 'Investigator deemed NCS' (Site from DM).	Mia Rountree (b) (4) (b) (4)	09 Dec 2020 16:27:01
User opened query 'Per CDM: Per CCG V2.0 page 53, SBP ≤ 89 or ≥141 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 13:35:54
User entered '147'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:47:34

US3912241

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User entered 'mmHg'	System	07 Dec 2020 17:47:34

US3912241

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '87'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:47:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User entered 'mmHg'	System	07 Dec 2020 17:47:34

FDA-CBER-2022-1614-3511784

US3912241

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30

US3912241

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:20:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30

US3912241

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:20:52

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:47:46

US3912241

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:20:52

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:47:46

US3912241

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:48:00

US3912241

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '04 Dec 2020'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:48:00

US3912241

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:52

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '14:37'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:48:00

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User entered '04 Dec 2020 14:37'	System	07 Dec 2020 17:48:00

US3912241

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:48:04

US3912241

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:52

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:30
User entered '1'	System	07 Dec 2020 17:48:04

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:19:44

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2020-12-10T15:06:36', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '055f1600-076f-4c15-b9d2-3686f1bbec1d'	System	10 Dec 2020 21:06:53
User entered 'No (N)'	System	10 Dec 2020 21:06:53

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2020-12-10T15:06:48', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '055f1600-076f-4c15-b9d2-3686f1bbec1d'	System	10 Dec 2020 21:06:53
User entered 'No (N)'	System	10 Dec 2020 21:06:53

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2020-12-10T15:06:51', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '055f1600-076f-4c15-b9d2-3686f1bbec1d'	System	10 Dec 2020 21:06:53
User entered '10 Dec 2020 15:06:51'	System	10 Dec 2020 21:06:53

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 12:19:44

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 12:19:44

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:19:44

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2020-12-16T00:41:41', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '26d36817-419d-4f4b-a3b9-07ae9a8028fc'	System	16 Dec 2020 06:42:32
User entered 'Yes (Y)'	System	16 Dec 2020 06:42:32

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2020-12-16T00:41:49', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '26d36817-419d-4f4b-a3b9-07ae9a8028fc'	System	16 Dec 2020 06:42:32
User entered 'No (N)'	System	16 Dec 2020 06:42:32

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2020-12-16T00:41:55', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '26d36817-419d-4f4b-a3b9-07ae9a8028fc'	System	16 Dec 2020 06:42:32
User entered 'No (N)'	System	16 Dec 2020 06:42:32

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2020-12-16T00:42:05', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '26d36817-419d-4f4b-a3b9-07ae9a8028fc'	System	16 Dec 2020 06:42:32
User entered 'Yes (Y)'	System	16 Dec 2020 06:42:32

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2020-12-16T00:42:13', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '26d36817-419d-4f4b-a3b9-07ae9a8028fc'	System	16 Dec 2020 06:42:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Dec 2020 06:42:32

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2020-12-16T00:42:22', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '26d36817-419d-4f4b-a3b9-07ae9a8028fc'	System	16 Dec 2020 06:42:32
User entered '16 Dec 2020 00:42:22'	System	16 Dec 2020 06:42:32

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 12:19:44

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 12:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:19:44

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2020-12-24T02:39:13', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'c6a8512b-d5ed-4328-80e6-7964d5b3822d'	System	24 Dec 2020 08:39:25
User entered 'No (N)'	System	24 Dec 2020 08:39:25

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2020-12-24T02:39:16', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'c6a8512b-d5ed-4328-80e6-7964d5b3822d'	System	24 Dec 2020 08:39:25
User entered 'No (N)'	System	24 Dec 2020 08:39:25

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2020-12-24T02:39:20', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'c6a8512b-d5ed-4328-80e6-7964d5b3822d'	System	24 Dec 2020 08:39:25
User entered '24 Dec 2020 02:39:20'	System	24 Dec 2020 08:39:25

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 12:19:44

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 12:19:44

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:19:44

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2021-01-01T02:15:27', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'ea3cfc17-b251-49a3-afbd-91d173a2dee6'	System	02 Jan 2021 05:23:34
User entered 'Yes (Y)'	System	02 Jan 2021 05:23:34

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2021-01-01T02:15:35', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'ea3cfc17-b251-49a3-afbd-91d173a2dee6'	System	02 Jan 2021 05:23:34
User entered 'No (N)'	System	02 Jan 2021 05:23:34

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2021-01-01T02:15:45', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'ea3cfc17-b251-49a3-afbd-91d173a2dee6'	System	02 Jan 2021 05:23:34
User entered 'No (N)'	System	02 Jan 2021 05:23:34

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2021-01-01T02:16:12', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'ea3cfc17-b251-49a3-afbd-91d173a2dee6'	System	02 Jan 2021 05:23:34
User entered 'Yes (Y)'	System	02 Jan 2021 05:23:34

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2021-01-01T23:23:19', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'ea3cfc17-b251-49a3-afbd-91d173a2dee6'	System	02 Jan 2021 05:23:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Jan 2021 05:23:34

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2021-01-01T23:23:23', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'ea3cfc17-b251-49a3-afbd-91d173a2dee6'	System	02 Jan 2021 05:23:34
User entered '01 Jan 2021 23:23:23'	System	02 Jan 2021 05:23:34

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 12:19:44

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 12:19:44

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:19:44

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2021-01-07T14:48:00', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '98974855-1cd0-4163-8f6b-a706e3dab2ec'	System	07 Jan 2021 20:48:12
User entered 'No (N)'	System	07 Jan 2021 20:48:12

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2021-01-07T14:48:04', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '98974855-1cd0-4163-8f6b-a706e3dab2ec'	System	07 Jan 2021 20:48:12
User entered 'No (N)'	System	07 Jan 2021 20:48:12

FDA-CBER-2022-1614-3511827

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2021-01-07T14:48:09', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: '98974855-1cd0-4163-8f6b-a706e3dab2ec'	System	07 Jan 2021 20:48:12
User entered '07 Jan 2021 14:48:09'	System	07 Jan 2021 20:48:12

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 12:19:44

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 12:19:44

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:19:44

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2021-01-13T16:21:40', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'c2c7fa6d-87ba-403a-94b1-0677cb585b9a'	System	19 Jan 2021 16:01:22
User entered 'No (N)'	System	19 Jan 2021 16:01:22

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2021-01-13T16:21:44', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'c2c7fa6d-87ba-403a-94b1-0677cb585b9a'	System	19 Jan 2021 16:01:22
User entered 'No (N)'	System	19 Jan 2021 16:01:22

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (466FBD30-9978-445A-9DDA-C3062E7F7FFB)', Time: '2021-01-13T16:21:53', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'c2c7fa6d-87ba-403a-94b1-0677cb585b9a'	System	19 Jan 2021 16:01:22
User entered '13 Jan 2021 16:21:53'	System	19 Jan 2021 16:01:22

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 12:19:44

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 12:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 12:19:44

FDA-CBER-2022-1614-3511837

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a00ea21733681ff)', Time: '2021-01-20T19:44:18', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'b2371b70-a907-497a-96b5-8e2523a2a833'	System	21 Jan 2021 04:40:39
User entered 'No (N)'	System	21 Jan 2021 04:40:39

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a00ea21733681ff)', Time: '2021-01-20T19:44:23', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'b2371b70-a907-497a-96b5-8e2523a2a833'	System	21 Jan 2021 04:40:39
User entered 'No (N)'	System	21 Jan 2021 04:40:39

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a00ea21733681ff)', Time: '2021-01-20T19:44:26', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'b2371b70-a907-497a-96b5-8e2523a2a833'	System	21 Jan 2021 04:40:39
User entered '20 Jan 2021 19:44:26'	System	21 Jan 2021 04:40:39

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 12:19:44

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 12:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 12:19:44

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a00ea21733681ff)', Time: '2021-01-27T00:22:36', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'c9d8acff-bb40-4966-9b60-84b4cfbc72cd'	System	27 Jan 2021 06:22:49
User entered 'No (N)'	System	27 Jan 2021 06:22:49

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a00ea21733681ff)', Time: '2021-01-27T00:22:42', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'c9d8acff-bb40-4966-9b60-84b4cfbc72cd'	System	27 Jan 2021 06:22:49
User entered 'No (N)'	System	27 Jan 2021 06:22:49

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a00ea21733681ff)', Time: '2021-01-27T00:22:46', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'c9d8acff-bb40-4966-9b60-84b4cfbc72cd'	System	27 Jan 2021 06:22:49
User entered '27 Jan 2021 00:22:46'	System	27 Jan 2021 06:22:49

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 12:19:44

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 12:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 12:19:44

FDA-CBER-2022-1614-3511849

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a00ea21733681ff)', Time: '2021-02-03T00:03:35', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'f2bb4807-92b0-428b-a313-aaea7b4b5678'	System	03 Feb 2021 06:03:51
User entered 'No (N)'	System	03 Feb 2021 06:03:51

US3912241

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:20:52

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a00ea21733681ff)', Time: '2021-02-03T00:03:40', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'f2bb4807-92b0-428b-a313-aaea7b4b5678'	System	03 Feb 2021 06:03:51
User entered 'No (N)'	System	03 Feb 2021 06:03:51

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a00ea21733681ff)', Time: '2021-02-03T00:03:46', User OID: 'PatientReportedOutcome (US3912241)', ODM File OID: 'f2bb4807-92b0-428b-a313-aaea7b4b5678'	System	03 Feb 2021 06:03:51
User entered '03 Feb 2021 00:03:46'	System	03 Feb 2021 06:03:51

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 12:19:44

US3912241
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:20:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:19:44
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 12:19:44

US3912241
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:20:52

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	04 Jan 2021 19:22:15

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '4 Jan 2021'	Monique Gawlik (b) (4)	04 Jan 2021 19:22:15

FDA-CBER-2022-1614-3511856

US3912241

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Monique Gawlik (b) (4)	04 Jan 2021 19:22:15

US3912241

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:20:52

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
User entered empty.	(b) (4) Monique Gawlik (b) (4)	04 Jan 2021 19:22:15

US3912241

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:20:52

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Monique Gawlik (b) (4)	04 Jan 2021 19:22:21

US3912241
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:20:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '1'	System	04 Jan 2021 19:22:21

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:20:52

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:20:37

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:20:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '2 Feb 2021'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:20:37

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:20:52

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Clinic (Clinic)'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:20:37

US3912241
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:20:52
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered 'UNBLND_DECIDE'	System	03 Feb 2021 15:20:37

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:20:52

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '2 Feb 2021'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:23:43

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:20:52

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:16:46
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:24:29

FDA-CBER-2022-1614-3511866

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:20:52

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:23:43

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:20:52

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	12 Mar 2021 19:16:46
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:24:29

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:20:52

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '2 Feb 2021'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:23:43

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:20:52

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Placebo (Placebo)'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:23:43

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:20:52

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Placebo (Placebo)'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:23:43

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:20:52

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Placebo (Placebo)'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:23:43

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:20:52

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:23:43

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:20:52

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '1'	System	03 Feb 2021 15:23:43

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:20:52

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	03 Feb 2021 15:23:43

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:24:00

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '2 Feb 2021'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:24:00

FDA-CBER-2022-1614-3511877

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '12:18'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:24:00

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:20:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '2 Feb 2021 12:18'	System	03 Feb 2021 15:24:00

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:20:52

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:24:14

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:20:52

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '2 Feb 2021'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:24:14

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:20:52

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '12:22'	Mia Rountree (b) (4) (b) (4)	03 Feb 2021 15:24:14

US3912241

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:20:52

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '2 Feb 2021 12:22'	System	03 Feb 2021 15:24:14

US3912241
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 10 Jun 2021 10:20:52
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User closed query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 68 and 82, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 06:13:37
Query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 68 and 82, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'Please accept data. Subject was contacted for Day 68 and reported being seen by hematologist as part of follow-up care for AE of pulmonary embolism. For Day 82 subject was seen for routine dental appointment.' (Site from DM).	Monique Gawlik (b) (4)	01 Apr 2021 00:05:07
User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 68 and 82, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 04:42:03
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:26:42
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:30:35

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
User closed query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 08:49:14
Query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'Subject was tested for COVID and the result was negative. ' (Site from DM).	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 22:38:55
User opened query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 19:32:19
DataPoint Verified.	Angela Kelly (b) (4) (b) (4)	18 Nov 2020 17:39:47
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Asthenia, LLT: Weakness generalized - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 23:35:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 23:35:34
Data point term sent to Coder	System	04 Nov 2020 23:35:06
User entered 'Generalized Weakness'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

US3912241
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:20:52

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered '3 Nov 2020'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	04 Nov 2020 23:34:24
User entered empty; reason for change Data Entry Error	Tina Rountree (b) (4)	04 Nov 2020 23:34:24
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	04 Nov 2020 23:34:08
User entered '18:30'	Tina Rountree (b) (4)	04 Nov 2020 23:34:08

FDA-CBER-2022-1614-3511891

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	04 Nov 2020 23:34:24
User entered '3 Nov 2020 18:30'	System	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:09:54
User closed query 'Per MM: please provide the end date.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 08:49:22
Query 'Per MM: please provide the end date.' answered with 'end date added' (Site from DM).	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 22:39:50
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	19 Dec 2020 22:39:36
DataPoint Un-verified.	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 22:39:36
User entered 'No (N)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 22:39:36
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	19 Dec 2020 22:39:28
User opened query 'Per MM: please provide the end date.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 19:32:11
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:09:55
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Dec 2020 22:40:20
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	19 Dec 2020 22:40:20
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Dec 2020 22:39:28
DataPoint Un-verified.	Tina Rountree (b) (4)	19 Dec 2020 22:39:28
User entered '06 Nov 2020' reason for change: Data Entry Error	Tina Rountree (b) (4)	19 Dec 2020 22:39:28
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered empty.	Tina Rountree (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered 'Grade 4 (Grade 4)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 09:16:20
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'This AE is not classified as serious however it did lead to an SAE of pulmonary embolism.' (Site from System).	Tina Rountree (b) (4)	04 Nov 2020 23:35:04
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	04 Nov 2020 23:34:08
User entered 'No (N)'	Tina Rountree (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered '0'	Tina Rountree (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered 'Related (RELATED)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

FDA-CBER-2022-1614-3511910

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered 'None (NONE)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered '1'	Tina Rountree (b) (4)	04 Nov 2020 23:34:08
	(b) (4)	

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:10:02
DataPoint Un-verified.	Tina Rountree (b) (4)	19 Dec 2020 22:40:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Tina Rountree (b) (4)	19 Dec 2020 22:40:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Tina Rountree (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:47
User entered empty.	Tina Rountree (b) (4)	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '0'	System	04 Nov 2020 23:34:08

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '1'	System	04 Nov 2020 23:34:08

US3912241

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:20:52

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

US3912241
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:20:52
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

US3912241
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:20:52
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
User closed query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 08:42:14
Query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'Subject was tested for covid in the hospital on 04NOV2020 and the result was negative. ' (Site from DM).	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:33:24
User opened query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 19:20:19
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:49:07
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Lower respiratory tract signs and symptoms, PT: Pleuritic pain, LLT: Pleural pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:37:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:37:07
Data point term sent to Coder	System	23 Nov 2020 15:43:33
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	23 Nov 2020 15:43:30
Coding entries removed.	Mia Rountree (b) (4) (b) (4)	23 Nov 2020 15:43:30
User entered 'CHEST PAIN (Pleural)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	23 Nov 2020 15:43:30
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 22:00:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 22:00:10
Data point term sent to Coder	System	20 Nov 2020 21:45:08

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Adverse event

Audit	User	Time (GMT)
Query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc).' canceled (Site from System).	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:45:03
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User opened query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc).' (Site from System).	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:02:42
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 23:37:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 23:37:36
Data point term sent to Coder	System	04 Nov 2020 23:37:08
User entered 'Chest pain'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered 'No (N)'	Tina Rountree (b) (4)	04 Nov 2020 23:36:53
	(b) (4)	

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered '03 Nov 2020'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

US3912241
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:20:52

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	04 Nov 2020 23:36:53

US3912241
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:20:52
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:10:30
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	23 Nov 2020 15:40:21
User entered 'No (N)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	23 Nov 2020 15:40:21
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:10:32
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	23 Nov 2020 15:40:34
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	23 Nov 2020 15:40:34
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	23 Nov 2020 15:40:21
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	23 Nov 2020 15:40:21
User entered '05 Nov 2020' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	23 Nov 2020 15:40:21
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

FDA-CBER-2022-1614-3511932

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	04 Nov 2020 23:36:53

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	Tina Rountree (b) (4)	04 Nov 2020 23:36:53
	(b) (4)	

US3912241
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:20:52
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

US3912241
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:20:52
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

US3912241
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:20:52

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

FDA-CBER-2022-1614-3511940

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered empty.	Tina Rountree (b) (4)	04 Nov 2020 23:36:53
	(b) (4)	

FDA-CBER-2022-1614-3511941

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered 'Related (RELATED)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

US3912241
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:20:52
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered 'None (NONE)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

US3912241
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 10:20:52
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:10:42
User closed query 'Per CDM: Other action taken is checked as 'None', however, there is a corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of "CHEST PAIN". Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:44:59
Query 'Per CDM: Other action taken is checked as 'None', however, there is a corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of "CHEST PAIN". Please clarify and update as appropriate.' answered with 'Data updated' (Site from DM).	Mia Rountree (b) (4) (b) (4)	23 Nov 2020 15:48:07
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	23 Nov 2020 15:48:00
User entered '0' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	23 Nov 2020 15:48:00
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User opened query 'Per CDM: Other action taken is checked as 'None', however, there is a corresponding medication recorded on the Prior and Concomitant Medications form with an Indication of "CHEST PAIN". Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 10:22:53
User entered '1'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:10:41
DataPoint Un-verified.	Mia Rountree (b) (4)	23 Nov 2020 15:48:00
User entered '1' reason for change: Data Entry Error	(b) (4) Mia Rountree (b) (4)	23 Nov 2020 15:48:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered '0'	Tina Rountree (b) (4)	04 Nov 2020 23:36:53
	(b) (4)	

FDA-CBER-2022-1614-3511950

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:10:44
DataPoint Un-verified.	Mia Rountree (b) (4)	23 Nov 2020 15:40:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Mia Rountree (b) (4) (b) (4)	23 Nov 2020 15:40:34
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:45
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:36:53

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '0'	System	04 Nov 2020 23:36:53

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '1'	System	04 Nov 2020 23:36:53

US3912241

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:20:52

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:04:52
User entered 'USA-US211-2020-mRNA-1273-P301000004'	System	05 Nov 2020 19:04:46
User entered 'New'	(b) (4), (b) (6)	05 Nov 2020 19:04:46

US3912241
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 10:20:52
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:30:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 20:56:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 20:56:35
Data point term sent to Coder	System	12 Nov 2020 20:47:04
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	12 Nov 2020 20:46:36
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	12 Nov 2020 20:46:36
User entered 'PULMONARY EMBOLISM, LLL' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	12 Nov 2020 20:46:36
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:37
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 23:53:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 23:53:31
Data point term sent to Coder	System	04 Nov 2020 23:53:21
User entered 'Pulmonary Embolism'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:39
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:40
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:42
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:48:52
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. If not updating the start date, please clarify.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:46:20
Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. If not updating the start date, please clarify.' answered with 'Updated correct start date' (Site from Safety).	Mia Rountree (b) (4) (b) (4)	20 Nov 2020 17:16:12
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	20 Nov 2020 17:15:40
User entered '03 Nov 2020' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	20 Nov 2020 17:15:40
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. If not updating the start date, please clarify.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:10:09
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:44
User entered '4 Nov 2020'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:46
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 10:20:52

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	04 Nov 2020 23:52:59

US3912241
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 10:20:52
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:11:52
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	20 Nov 2020 17:21:59
User entered 'No (N)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	20 Nov 2020 17:21:59
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:48
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:11:53
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:45:26
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'returned to baseline' (Site from Safety).	Mia Rountree (b) (4) (b) (4)	20 Nov 2020 17:22:21
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	20 Nov 2020 17:21:59
User entered '9 Nov 2020' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	20 Nov 2020 17:21:59
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:09:25
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:49
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 10:20:52

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:51
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:52
User entered 'Grade 4 (Grade 4)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 10:20:52
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:53
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:55
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:57
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
Query 'Per CDM: Reponse noted. However, Kindly keep this query in open state until appropriate information is available and EDC is updated. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 14:39:25
User opened query 'Per CDM: Reponse noted. However, Kindly keep this query in open state until appropriate information is available and EDC is updated. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 12:44:04
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 12:43:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:23:58
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject is still in the hospital. Will enter discharge date when known. ' (Site from System).	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:54:40
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	04 Nov 2020 23:52:59
User entered '1'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:00
User entered '4 Nov 2020'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:14:53
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	23 Nov 2020 15:53:33
User entered '05 Nov 2020' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	23 Nov 2020 15:53:33
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:01
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:03
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	06 Nov 2020 03:09:37
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	06 Nov 2020 03:09:37
User entered 'No (N)' reason for change: Data Entry Error	Tina Rountree (b) (4)	06 Nov 2020 03:09:37
	(b) (4)	
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	04 Nov 2020 23:52:59
User entered 'Unknown (UNK)'	Tina Rountree (b) (4)	04 Nov 2020 23:52:59
	(b) (4)	

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 01:29:34
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:05
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:07
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:09
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 22:09:25
User closed query 'PV Query: Please provide rationale for attribution of relatedness to mRNA-1273 or placebo. Please leave query open until hematology results have been received.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 15:32:29
Query 'PV Query: Please provide rationale for attribution of relatedness to mRNA-1273 or placebo. Please leave query open until hematology results have been received.' answered with 'After speaking with hematologist that subject saw for follow up care, SAE deemed not related based on updated information. ' (Site from Safety).	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 22:41:54
DataPoint Un-verified.	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 22:41:47
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 22:41:47
User opened query 'PV Query: Please provide rationale for attribution of relatedness to mRNA-1273 or placebo. Please leave query open until hematology results have been received.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 19:33:58
User closed query 'PV Query: Please provide rationale for attribution of relatedness to mRNA-1273 or placebo.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:46:02
Query 'PV Query: Please provide rationale for attribution of relatedness to mRNA-1273 or placebo.' answered with 'Until more blood studies are done with hematologist, investigator cannot determine that is not related. Subject has an appointment with hematologist on 25 NOV 2020.' (Site from Safety).	Mia Rountree (b) (4) (b) (4)	20 Nov 2020 17:23:49
User opened query 'PV Query: Please provide rationale for attribution of relatedness to mRNA-1273 or placebo.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:09:50
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:11
User entered 'Related (RELATED)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:13
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
User closed query 'Per CDM: Please complete also the Dosing Discontinuation form, if applicable, as the investigational product is withdrawn due to this Adverse event (AE#3). Please review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 15:32:04
Query 'Per CDM: Please complete also the Dosing Discontinuation form, if applicable, as the investigational product is withdrawn due to this Adverse event (AE#3). Please review and update accordingly. Thank you.' answered with 'Data updated in Dosing Continuation folder ' (Site from DM).	Mia Rountree (b) (4) (b) (4)	20 Nov 2020 17:30:38
User opened query 'Per CDM: Please complete also the Dosing Discontinuation form, if applicable, as the investigational product is withdrawn due to this Adverse event (AE#3). Please review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 16:58:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:06:25
DataPoint Un-verified.	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:13:00
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:13:00
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:24:15
User entered 'None (NONE)'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:26:18
User entered '0'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 10:20:52
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:26:19
User entered '1'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 10:20:52
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:15:54
User closed query 'Per DM CLR - RQ: Site's response noted. However, CT Scan is a Diagnostic procedure rather than therapeutic. Please update to record the therapeutic procedure performed for this AE as applicable or update to un-select Concomitant Procedure. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 11:14:18
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
Query 'Per DM CLR - RQ: Site's response noted. However, CT Scan is a Diagnostic procedure rather than therapeutic. Please update to record the therapeutic procedure performed for this AE as applicable or update to un-select Concomitant Procedure. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 21:39:55
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	24 Mar 2021 21:39:37
User entered '0' reason for change: New Information	Sandra Clancy (b) (4) (b) (4)	24 Mar 2021 21:39:37
User opened query 'Per DM CLR - RQ: Site's response noted. However, CT Scan is a Diagnostic procedure rather than therapeutic. Please update to record the therapeutic procedure performed for this AE as applicable or update to un-select Concomitant Procedure. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 16:06:42
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 05:52:39
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'the CT of the chest performed on 04Nov2020 is the procedure.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 22:26:08

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Concomitant Procedure

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 03:37:51
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:39:56
DataPoint Un-verified.	Sandra Clancy (b) (4)	16 Nov 2020 18:17:57
User entered '1' reason for change: New Information	Sandra Clancy (b) (4)	16 Nov 2020 18:17:57
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:26:21
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:15:01
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:45:40
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Updated information' (Site from Safety).	Mia Rountree (b) (4) (b) (4)	20 Nov 2020 17:24:30
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	20 Nov 2020 17:21:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	20 Nov 2020 17:21:59
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:09:38
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:26:23
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 23:53:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 23:53:45
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:53:45
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 23:52:59
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 10:20:52
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:26:24
User entered empty.	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
User closed query 'PV Query: Please provide the office visit notes and the results of any additional outpatient laboratory/diagnostic work-up from the subject's follow-up with hematology and/or primary care to safety_Moderna@iqvia.com, when available. Please leave query open until provided or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:19:58
Query 'PV Query: Please provide the office visit notes and the results of any additional outpatient laboratory/diagnostic work-up from the subject's follow-up with hematology and/or primary care to safety_Moderna@iqvia.com, when available. Please leave query open until provided or, if unable to obtain, please state so.' answered with 'will fax records today 21Dec2020' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	21 Dec 2020 22:00:22
User opened query 'PV Query: Please provide the office visit notes and the results of any additional outpatient laboratory/diagnostic work-up from the subject's follow-up with hematology and/or primary care to safety_Moderna@iqvia.com, when available. Please leave query open until provided or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 19:34:22
User closed query 'PV Query: Please provide the office visit notes and the results of any additional outpatient laboratory/diagnostic work-up from the subject's follow-up with hematology and/or primary care to safety_Moderna@iqvia.com, when available. Please leave query open until provided or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:14:37
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 13:14:32

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide the office visit notes and the results of any additional outpatient laboratory/diagnostic work-up from the subject's follow-up with hematology and/or primary care to safety_Moderna@iqvia.com, when available. Please leave query open until provided or, if unable to obtain, please state so.' answered with 'Referral to hematology is scheduled for 11/25/2020 ' (Site from Safety).	Mia Rountree (b) (4) (b) (4)	24 Nov 2020 00:33:37
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Serology- CoV-2 (PCR) (Negative)' (Site from Safety).	Mia Rountree (b) (4) (b) (4)	23 Nov 2020 15:51:26
User opened query 'PV Query: Please provide the office visit notes and the results of any additional outpatient laboratory/diagnostic work-up from the subject's follow-up with hematology and/or primary care to safety_Moderna@iqvia.com, when available. Please leave query open until provided or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:10:31
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:09:09
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:26:25

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Narrative

Audit	User	Time (GMT)
User entered 'Subject called study site on the morning of 04 November 2020 to report that he was feeling generalized weakness and chest pain. Subject called the hospital to report these symptoms and was advised to stay home. Several hours later when subject was still experiencing symptoms he called EMS and was transported to the hospital via ambulance. Subject called site again in the afternoon to report that he has a blood clot in his lungs and is taking a blood thinner. He states that he was admitted to the hospital. Subject was in good spirits and talkative. He reported feeling better. Site staff asked subject to have the attending physician call PI when available.'	Tina Rountree (b) (4) (b) (4)	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '1'	System	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:20:52

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '1'	System	04 Nov 2020 23:52:59

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '0'	System	04 Nov 2020 23:52:59

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:41:23
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:04
User entered 'USA-US211-2020-mRNA-1273-P301000007'	System	06 Dec 2020 17:44:59
User entered 'New'	(b) (4), (b) (6)	06 Dec 2020 17:44:59

US3912241
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:20:52
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
User coded data point as SOC: Psychiatric disorders, HLGT: Schizophrenia and other psychotic disorders, HLT: Schizophrenia NEC, PT: Schizophrenia, LLT: Schizophrenia aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 14:20:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 14:20:59
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:41:25
Data point term sent to Coder	System	05 Dec 2020 18:45:05
User entered 'worsening of schizophrenia psychotic disorder'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:41:27
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:41:29
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

FDA-CBER-2022-1614-3512000

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:41:31
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:20:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:41:32
User entered '1 Dec 2020'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:41:35
User entered empty.	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	05 Dec 2020 18:44:30

US3912241
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:20:52
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:11:00
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	18 Jan 2021 22:12:46
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	18 Jan 2021 22:12:46
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	18 Jan 2021 22:12:46
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	18 Jan 2021 22:11:58
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:41:37
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:11:02
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 13:35:58
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	18 Jan 2021 22:12:55
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	18 Jan 2021 22:11:58
User entered '4 Dec 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	18 Jan 2021 22:11:58
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:27:30
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:41:39
User entered empty.	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:20:52

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:41:41
User entered empty.	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
User closed query 'PV Query: Please confirm the severity of the event, since the event lead to hospitalization.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:21:11
Query 'PV Query: Please confirm the severity of the event, since the event lead to hospitalization.' answered with 'Severity grade is confirmed as correct' (Site from Safety).	Mia Rountree (b) (4) (b) (4)	20 Jan 2021 14:48:58
User opened query 'PV Query: Please confirm the severity of the event, since the event lead to hospitalization.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:29:14
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:41:43
User entered 'Grade 3/Severe (Grade 3/Severe)'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:41:46
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:20:52
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:41:49
User entered '0'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:41:50
User entered '0'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:20:52
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:41:52
User entered '1'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:41:53
User entered '1 Dec 2020'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:41:55
User entered '4 Dec 2020'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:41:57
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:07
User entered empty.	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:09
User entered '0'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:10
User entered '0'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:11
User entered '0'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:41:58
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:20:52
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:00
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
User closed query 'PV Query: Please confirm if a second dose of study drug was given and if so, on what date?' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 13:36:10
Query 'PV Query: Please confirm if a second dose of study drug was given and if so, on what date?' answered with 'this is correct as subject did not receive second dose.' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	18 Jan 2021 16:50:23
User opened query 'PV Query: Please confirm if a second dose of study drug was given and if so, on what date?' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 16:07:06
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:02
User entered 'Not Applicable (NOT APPLICABLE)'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User closed query 'Per DM CLR: Is this adverse event serious? = YES. Please review and please note, there is no listed treatment for this SAE and treatment is expected. Please review and update to record the corresponding treatment as applicable. Otherwise, clarify reason why no treatment was needed/' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 11:23:32
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
Query 'Per DM CLR: Is this adverse event serious? = YES. Please review and please note, there is no listed treatment for this SAE and treatment is expected. Please review and update to record the corresponding treatment as applicable. Otherwise, clarify reason why no treatment was needed/' answered with 'the event meets definition of SAE due to hospitalization. While treatment may be expected, the subject refused treatment which is not to say it wasn't needed.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	24 Mar 2021 21:45:39
User opened query 'Per DM CLR: Is this adverse event serious? = YES. Please review and please note, there is no listed treatment for this SAE and treatment is expected. Please review and update to record the corresponding treatment as applicable. Otherwise, clarify reason why no treatment was needed/' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 16:07:34
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:11:01
DataPoint Un-verified.	Tina Rountree (b) (4) (b) (4)	22 Dec 2020 19:25:59
User entered '1' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	22 Dec 2020 19:25:59
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:14
User entered '0'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:16
User entered '0'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:20:52
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
User closed query 'Per CDM : Please note that Other Action Taken = Concomitant Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 10:01:58
Query 'Per CDM : Please note that Other Action Taken = Concomitant Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate. Thank you.' answered with 'no con procedure' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	18 Jan 2021 16:51:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:11:05
DataPoint Un-verified.	Tina Rountree (b) (4) (b) (4)	22 Dec 2020 19:25:59
User entered '0' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	22 Dec 2020 19:25:59
User opened query 'Per CDM : Please note that Other Action Taken = Concomitant Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 16:03:04
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:19
User entered '1'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:20:52
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:11:11
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 13:36:14
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	18 Jan 2021 22:13:37
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	18 Jan 2021 22:11:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	18 Jan 2021 22:11:58
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:27:59
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:21
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:23
User entered empty.	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:20:52
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 13:39:47
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 13:39:45
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 13:39:43
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'subject denies any medications' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 22:05:31
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'unavailable' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 21:58:52
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'unknown' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	21 Jan 2021 21:58:43
User closed query 'PV Query: Please confirm whether pulmonary embolism meets criteria of SAE/AE. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 13:36:17
Query 'PV Query: Please confirm whether pulmonary embolism meets criteria of SAE/AE. If not, please explain.' answered with 'this query is not for this event -- please place in the appropriate eCRF-thanks' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	18 Jan 2021 22:14:30

US3912241
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:20:52
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm whether pulmonary embolism meets criteria of SAE/AE. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:33:50
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:28:50
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:28:16
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:27:15
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:24
User entered 'Subject arrived for day 57 visit and reported to staff that he had just been released from cross creek hospital which is a psychiatric hospital. Subject brought his discharge paperwork and site was able to obtain a copy. It states that subject was admitted due to being a danger to himself. His behavioral health diagnosis was schizophrenia psychotic disorder. Subject denied this as medical history, however, after further questioning subject stated that he has been institutionalized a total of 4 times since 2006. Subject denied being a danger to himself. He stated that he admitted himself to the hospital to get away from all of the people at his house. Condition added to medical history with a start date of 2006. Detailed records surrounding the in patient hospitalization were requested.'	Tina Rountree (b) (4) (b) (4)	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '1'	System	05 Dec 2020 18:44:30

Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 10:20:52
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '1'	System	05 Dec 2020 18:44:30

US3912241

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:20:52

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '0'	System	05 Dec 2020 18:44:30

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:15
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermal and epidermal conditions NEC, PT: Dry skin, LLT: Dry skin - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 18:07:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 18:07:47
Data point term sent to Coder	System	07 Dec 2020 17:42:24
User entered 'Dry skin'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:16
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:18
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:19
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:21
User entered '21 Nov 2020'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:22
User entered empty.	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User closed query 'Per DM CLR: Please review the status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm if this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 11:14:04
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
Query 'Per DM CLR: Please review the status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm if this AE is still ongoing.' answered with 'the event was not closed prior to the subject being withdrawn from the study. Date of study discontinuation is 04feb2021.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	24 Mar 2021 21:53:11
User opened query 'Per DM CLR: Please review the status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm if this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 16:05:04
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:24
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:25
User entered empty.	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:27
User entered empty.	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	07 Dec 2020 17:41:25

FDA-CBER-2022-1614-3512045

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:30
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 10:20:52
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:41
User entered '0'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:41
User entered '0'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:46:41
User entered '0'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 10:20:52
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:41
User entered '0'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:41
User entered '0'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:41
User entered '0'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:32
User entered 'Not Related (NOT RELATED)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:33
User entered 'Not Related (NOT RELATED)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:34
User entered 'Not Applicable (NOT APPLICABLE)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:37
User entered '1'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:41
User entered '0'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:41
User entered '0'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:36
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:46:41
User entered empty.	Mia Rountree (b) (4) (b) (4)	07 Dec 2020 17:41:25

US3912241

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:20:52

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '0'	System	07 Dec 2020 17:41:25

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '0'	System	07 Dec 2020 17:41:25

Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 10:20:52
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:20:52

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:26:49
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 13:56:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 13:56:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:56:07
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 13:56:04
User entered empty.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:56:04

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 06:55:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 06:55:34
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User closed query 'Per Adverse Event Progress Note dated 5Nov2020 15:30, subject reported starting Lovenox and Norco. Please update concomitant medications eCRF when dosing information becomes available. Thank you!' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 14:56:02
Query 'Per Adverse Event Progress Note dated 5Nov2020 15:30, subject reported starting Lovenox and Norco. Please update concomitant medications eCRF when dosing information becomes available. Thank you!' answered with 'con meds updated' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	12 Nov 2020 20:38:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:11:41
User opened query 'Per Adverse Event Progress Note dated 5Nov2020 15:30, subject reported starting Lovenox and Norco. Please update concomitant medications eCRF when dosing information becomes available. Thank you!' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 19:43:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN CUPAL [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:33:32

FDA-CBER-2022-1614-3512071

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:52

Name of Medication

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:33:32
Data point term sent to Coder	System	14 Oct 2020 13:59:35
User entered 'Aspirin'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:59:25

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:52

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:11:44
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:59:25

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:11:45
User entered 'Generalized body aches'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:59:25

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:52

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:11:51
User entered '325'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:59:25

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:52

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:11:52
User entered 'tablet (TABLET)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:59:25

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered empty.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:59:25

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:52

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:11:54
User entered 'as needed (PRN)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:59:25

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered empty.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:59:25

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:52

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:11:56
User entered 'Oral (ORAL)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:59:25

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered empty.	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:59:25

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:11:57
User entered 'un UNK 2000'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:59:25

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered '0'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:59:25

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:52

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:12:02
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:59:25

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:52

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered empty.	Mia Rountree (b) (4)	14 Oct 2020 13:59:25
	(b) (4)	

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:12:04
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	14 Oct 2020 13:59:25

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	14 Oct 2020 13:59:25

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	14 Oct 2020 13:59:25

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:20:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	14 Oct 2020 13:59:25

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 08:39:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 08:39:39
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 14:55:36
Data point term sent to Coder	System	12 Nov 2020 20:42:50
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	12 Nov 2020 20:41:57
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	12 Nov 2020 20:41:57
User entered 'ENOXAPARIN SODIUM (lovenox)' reason for change: Per Query Resolution	Sandra Clancy (b) (4) (b) (4)	12 Nov 2020 20:41:57
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:12:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:10:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:10:29
Data point term sent to Coder	System	07 Nov 2020 15:26:03
User entered 'Enoxaparin Sodium'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:25:46

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:52

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:12:18
User entered 'No (N)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:25:46

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:12:19
User entered 'Pulmonary Embolism'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:25:46

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:52

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:12:24
User entered '100'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:25:46

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:52

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:12:25
User entered 'mg (mg)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:25:46

FDA-CBER-2022-1614-3512094

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered empty.	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:25:46

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:52

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:12:27
User entered 'twice daily (BID)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:25:46

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered empty.	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:25:46

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:52

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:12:30
User entered 'Subcutaneous (SUBCUTANEOUS)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:25:46

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered empty.	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:25:46

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:12:32
User entered '04 Nov 2020'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:25:46

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered '0'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:25:46

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:52

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:12:35
User entered 'No (N)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:25:46

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:52

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:12:34
User entered '05 Nov 2020'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:25:46

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:12:37
User entered 'No (N)' reason for change: Data Entry Error	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:27:37
User entered 'Yes (Y)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:25:46

FDA-CBER-2022-1614-3512104

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '2'	System	07 Nov 2020 15:25:46

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '1'	System	07 Nov 2020 15:25:46

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:20:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '804 (804)'	System	07 Nov 2020 15:25:46

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:12:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:14:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:14:30
Data point term sent to Coder	System	07 Nov 2020 15:28:04
User entered 'Ketorolac Tromethamine'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:27:22

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:52

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:12:54
User entered 'No (N)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:27:22

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:12:55
User entered 'Chest Pain'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:27:22

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:52

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:12:57
User entered '10'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:27:22

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:52

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:12:59
User entered 'mg (mg)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:27:22

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered empty.	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:27:22

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:52

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:13:00
User entered 'once (ONCE)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:27:22

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered empty.	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:27:22

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:52

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:13:02
User entered 'Intravenous (INTRAVENOUS)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:27:22

FDA-CBER-2022-1614-3512116

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered empty.	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:27:22

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:13:06
User entered '04 Nov 2020'	Timothy Vachris (b) (4)	07 Nov 2020 15:27:22
	(b) (4)	

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered '0'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:27:22

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:52

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:13:08
User entered 'No (N)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:27:22

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:52

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:13:05
User entered '04 Nov 2020'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:27:22

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:13:10
User entered 'No (N)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:27:22

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	07 Nov 2020 15:27:22

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:20:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	07 Nov 2020 15:27:22

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:20:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	07 Nov 2020 15:27:22

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:13:26
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:14:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:14:28
Data point term sent to Coder	System	07 Nov 2020 15:30:05
User entered 'Iopamidol'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:29:33

FDA-CBER-2022-1614-3512126

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:52

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:13:28
User entered 'No (N)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:29:33

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:13:31
User entered 'Diagnostic Agent for CTA'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:29:33

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:52

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:13:32
User entered '100'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:29:33

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:52

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:13:34
User entered 'mL (mL)'	Timothy Vachris (b) (4)	07 Nov 2020 15:29:33
	(b) (4)	

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered empty.	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:29:33

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:52

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:13:36
User entered 'once (ONCE)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:29:33

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered empty.	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:29:33

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:13:37
User entered 'Intravenous (INTRAVENOUS)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:29:33

FDA-CBER-2022-1614-3512134

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered empty.	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:29:33

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:13:39
User entered '04 Nov 2020'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:29:33

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered '0'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:29:33

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:52

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:13:41
User entered 'No (N)'	Timothy Vachris (b) (4)	07 Nov 2020 15:29:33

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:52

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:13:43
User entered '04 Nov 2020'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:29:33

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:13:44
User entered 'No (N)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:29:33

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	07 Nov 2020 15:29:33

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	07 Nov 2020 15:29:33

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:20:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	07 Nov 2020 15:29:33

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:13:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE PHOSPHATE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL W/CODEINE NO. 3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:19:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:19:31
Data point term sent to Coder	System	07 Nov 2020 15:37:06
User entered 'Tylenol/ Codeine #3'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:36:53

FDA-CBER-2022-1614-3512144

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:52

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:13:58
User entered 'No (N)'	Timothy Vachris (b) (4)	07 Nov 2020 15:36:53

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:14:00
User entered 'Chest Pain'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:36:53

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:52

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:14:02
User entered '300/30'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:36:53

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:52

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:14:04
User entered 'mg (mg)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:36:53

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered empty.	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:36:53

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:52

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:14:06
User entered 'other (OTHER)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:36:53

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:14:07
User entered '1-2 tablets every 6 hours as needed'	Timothy Vachris (b) (4)	07 Nov 2020 15:36:53

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:52

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:14:09
User entered 'Oral (ORAL)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:36:53

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered empty.	Timothy Vachris (b) (4)	07 Nov 2020 15:36:53

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:14:11
User entered '05 Nov 2020'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:36:53

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered '0'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:36:53

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:52

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:41:47
User closed query 'Per source documentation, TYLENOL/ CODEINE #3 end date was 05Nov2020. Please clarify, or correct. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 18:41:45
Query 'Per source documentation, TYLENOL/ CODEINE #3 end date was 05Nov2020. Please clarify, or correct. Thank you! ' answered with 'Data corrected ' (Site from CRA).	Mia Rountree (b) (4) (b) (4)	11 Nov 2020 17:06:24
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	11 Nov 2020 17:06:16
User entered 'No (N)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	11 Nov 2020 17:06:16
User opened query 'Per source documentation, TYLENOL/ CODEINE #3 end date was 05Nov2020. Please clarify, or correct. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 23:16:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:14:13
User entered 'Yes (Y)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:36:53

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:52

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:41:49
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	11 Nov 2020 17:06:16
User entered '05 Nov 2020' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	11 Nov 2020 17:06:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered empty.	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:36:53

FDA-CBER-2022-1614-3512157

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:14:15
User entered 'No (N)'	Timothy Vachris (b) (4)	07 Nov 2020 15:36:53

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	07 Nov 2020 15:36:53

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	07 Nov 2020 15:36:53

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:20:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered empty.	System	07 Nov 2020 15:36:53

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:15:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:08:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 11:08:28
Data point term sent to Coder	System	07 Nov 2020 15:41:07
User entered 'Apixaban (Eliquis)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:40:10

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:52

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:15:14
User entered 'No (N)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:40:10

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:15:15
User entered 'Pulmonary Embolism'	Timothy Vachris (b) (4)	07 Nov 2020 15:40:10
	(b) (4)	

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:52

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:15:19
User entered '5'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:40:10

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:52

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:15:20
User entered 'mg (mg)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:40:10

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered empty.	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:40:10

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:52

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:15:22
User entered 'twice daily (BID)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:40:10

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered empty.	Timothy Vachris (b) (4)	07 Nov 2020 15:40:10

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:52

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:15:23
User entered 'Oral (ORAL)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:40:10

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered empty.	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:40:10

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:52

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:15:26
User entered '05 Nov 2020'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:40:10

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered '0'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:40:10

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:52

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 16:29:17
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'Medication is confirmed as still ongoing' (Site from DM).	Mia Rountree (b) (4) (b) (4)	13 Jan 2021 20:15:07
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 15:33:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:15:29
User entered 'Yes (Y)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:40:10

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:52

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:10
User entered empty.	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:40:10

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:52

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:15:31
User entered 'No (N)'	Timothy Vachris (b) (4) (b) (4)	07 Nov 2020 15:40:10

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:52

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '2'	System	07 Nov 2020 15:40:10

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:52

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '1'	System	07 Nov 2020 15:40:10

US3912241

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:20:52

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '804 (804)'	System	07 Nov 2020 15:40:10

US3912241

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:20:52

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:24
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	16 Nov 2020 18:23:44

US3912241

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:20:52

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	24 Mar 2021 22:48:57
Signature has been broken.	Sandra Clancy (b) (4) (b) (4)	24 Mar 2021 21:41:46
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:32
User entered '04 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	16 Nov 2020 18:26:32

US3912241

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:20:52

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:32
User entered 'Doppler ultrasound'	Sandra Clancy (b) (4) (b) (4)	16 Nov 2020 18:26:32

US3912241

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:20:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:32
User entered 'Diagnostic (DIAGNOSTIC)'	Sandra Clancy (b) (4) (b) (4)	16 Nov 2020 18:26:32

US3912241

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:20:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:32
User entered empty.	Sandra Clancy (b) (4) (b) (4)	16 Nov 2020 18:26:32

US3912241

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:20:52

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:34
User entered '04 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	16 Nov 2020 18:33:30

US3912241

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:20:52

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:34
User entered 'chest x-ray'	Sandra Clancy (b) (4)	16 Nov 2020 18:33:30
	(b) (4)	

US3912241

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:20:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:34
User entered 'Diagnostic (DIAGNOSTIC)'	Sandra Clancy (b) (4)	16 Nov 2020 18:33:30

US3912241

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:20:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:34
User entered empty.	Sandra Clancy (b) (4)	16 Nov 2020 18:33:30
	(b) (4)	

US3912241

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:20:52

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:36
User entered '04 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	16 Nov 2020 18:34:55

US3912241

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:20:52

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:36
User entered 'transthoracic echocardiography'	Sandra Clancy (b) (4) (b) (4)	16 Nov 2020 18:34:55

US3912241

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:20:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:36
User entered 'Diagnostic (DIAGNOSTIC)'	Sandra Clancy (b) (4) (b) (4)	16 Nov 2020 18:34:55

US3912241

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:20:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:36
User entered empty.	Sandra Clancy (b) (4)	16 Nov 2020 18:34:55
	(b) (4)	

US3912241

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:20:52

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User closed query 'Per SAE Worsening of Schizophrenia psychotic disorder, concomitant therapy was indicated but has not been added to EDC. Please add, or clarify. Thank you!' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 13:53:37
Query 'Per SAE Worsening of Schizophrenia psychotic disorder, concomitant therapy was indicated but has not been added to EDC. Please add, or clarify. Thank you!' answered with 'please place query in the appropriate eCRF.' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 22:29:21
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:01:56
User opened query 'Per SAE Worsening of Schizophrenia psychotic disorder, concomitant therapy was indicated but has not been added to EDC. Please add, or clarify. Thank you!' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 18:58:20
DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 18:56:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:37
User entered '04 Nov 2020'	Sandra Clancy (b) (4) (b) (4)	16 Nov 2020 18:37:46

US3912241

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:20:52

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:01:56
DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 18:56:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:37
User entered 'electrocardiogram'	Sandra Clancy (b) (4) (b) (4)	16 Nov 2020 18:37:46

US3912241

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:20:52

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:01:56
DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 18:56:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:37
User entered 'Diagnostic (DIAGNOSTIC)'	Sandra Clancy (b) (4) (b) (4)	16 Nov 2020 18:37:46

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:01:56
DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 18:56:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:37
User entered empty.	Sandra Clancy (b) (4) (b) (4)	16 Nov 2020 18:37:46

US3912241

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:20:52

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 20:25:25
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:16:10
User entered '04 Nov 2020'	Mia Rountree (b) (4) (b) (4)	20 Nov 2020 17:30:04

US3912241

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:20:52

Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User closed query 'Per CDM: Primary reason for dosing discontinuation is recorded as SAE (specify). However, End of Study/ Study Discontinuation page reason for Discontinuation is recorded as Physician decision (specify). Please review and reconcile or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 07:56:30
Query 'Per CDM: Primary reason for dosing discontinuation is recorded as SAE (specify). However, End of Study/ Study Discontinuation page reason for Discontinuation is recorded as Physician decision (specify). Please review and reconcile or else clarify. Thank you.' answered with 'correct - this dosing is for Part A; subject did not receive a 2nd injection due to the SAE. Study discontinuation is correct as d/c for physician decision.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	24 Mar 2021 22:02:29
User opened query 'Per CDM: Primary reason for dosing discontinuation is recorded as SAE (specify). However, End of Study/ Study Discontinuation page reason for Discontinuation is recorded as Physician decision (specify). Please review and reconcile or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 05:39:09
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 20:25:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:15:31
User entered 'SAE (specify) (SAE)'	Mia Rountree (b) (4) (b) (4)	20 Nov 2020 17:30:04

US3912241

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:20:52

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 20:25:29
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 20:23:27
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 20:02:32
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #3). Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 13:42:30
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #3). Thank you. ' answered with 'Data updated' (Site from DM).	Mia Rountree (b) (4) (b) (4)	08 Mar 2021 17:32:45
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	08 Mar 2021 17:32:36
Signature has been broken.	Mia Rountree (b) (4) (b) (4)	08 Mar 2021 17:32:36
User entered 'AE #3' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	08 Mar 2021 17:32:36
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #3). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:25:22
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User closed query 'Per CDM: Per CCG V2.0 Page 44, If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline # in the Other, specify field. Kindly Do not record the Adverse Event term or include any other text as it is there Primary reason". Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 09:53:04
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 13:54:03
User closed query 'Per source documentation and EDC, log line of SAE related to dosing discontinuation is 3. Please clarify, or correct. Thank you!' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 13:54:00

US3912241

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:20:52

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Query 'Per source documentation and EDC, log line of SAE related to dosing discontinuation is 3. Please clarify, or correct. Thank you!' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 22:33:28
Query 'Per CDM: Per CCG V2.0 Page 44, If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline # in the Other, specify field. Kindly Do not record the Adverse Event term or include any other text as it is there Primary reason". Please review and update as appropriate. Thank you' answered with 'corrected' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 22:33:19
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 22:33:12
User entered 'AE line 3' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	25 Jan 2021 22:33:12
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:05:15
User opened query 'Per source documentation and EDC, log line of SAE related to dosing discontinuation is 3. Please clarify, or correct. Thank you!' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 18:55:28
User opened query 'Per CDM: Per CCG V2.0 Page 44, If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline # in the Other, specify field. Kindly Do not record the Adverse Event term or include any other text as it is there Primary reason". Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:18:32
User closed query 'Per query below, Do not record the Adverse Event term or include any other text. Please remove "PULMONARY EMBOLISM LLL". Thank you!' (Site from CRA).	(b) (4), (b) (6)	05 Dec 2020 06:37:56
Query 'Per query below, Do not record the Adverse Event term or include any other text. Please remove "PULMONARY EMBOLISM LLL". Thank you!' answered with 'corrected' (Site from CRA).	Sandra Clancy (b) (4) (b) (4)	04 Dec 2020 17:34:20

US3912241

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:20:52

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	04 Dec 2020 17:34:11
User entered 'SAE' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	04 Dec 2020 17:34:11
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	04 Dec 2020 17:33:56
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	04 Dec 2020 17:33:56
User entered empty; reason for change Data Entry Error	Sandra Clancy (b) (4) (b) (4)	04 Dec 2020 17:33:56
User opened query 'Per query below, Do not record the Adverse Event term or include any other text. Please remove "PULMONARY EMBOLISM LLL". Thank you!' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 18:29:57
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:28:48
User closed query 'Per CDM: Per CCG V2.0 Page 44, If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline #/SAE Logline # in the Other, specify field. Do not record the Adverse Event term or include any other text". Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 06:06:23
Query 'Per CDM: Per CCG V2.0 Page 44, If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline #/SAE Logline # in the Other, specify field. Do not record the Adverse Event term or include any other text". Please review and update as appropriate. Thank you. ' answered with 'Updated information ' (Site from DM).	Mia Rountree (b) (4) (b) (4)	25 Nov 2020 16:27:50
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	25 Nov 2020 16:27:39
User entered 'Adverse event #3 Pulmonary embolism LLL' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	25 Nov 2020 16:27:39

US3912241

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:20:52

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCG V2.0 Page 44, If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline #/SAE Logline # in the Other, specify field. Do not record the Adverse Event term or include any other text". Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 10:36:59
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:15:29
User entered 'Pulmonary Embolism, LLL'	Mia Rountree (b) (4) (b) (4)	20 Nov 2020 17:30:04

US3912241
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 10:20:52
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:33:58
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '4 Feb 2021'	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 01:07:02

US3912241

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:20:52

Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:33:58
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 01:07:02

US3912241

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:20:52

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:33:58
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered 'subject was withdrawn due to his refusal to medically manage his mental health (schizophrenia); realizing that this condition will likely worsen without treatment, subject withdrawn.'	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 01:07:02

US3912241
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 10:20:52

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:33:58
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 01:07:02

US3912241

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:20:52

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:33:58
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 01:07:02

US3912241

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:20:52

Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:33:58
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 01:07:02

US3912241

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:20:52

Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 21:33:58
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered empty.	Sandra Clancy (b) (4) (b) (4)	06 Feb 2021 01:07:02

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'USA-US211-2020-MRNA-1273-P301000004'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Yes (Y)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Yes (Y)'	System	05 Nov 2020 19:04:46

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Mark'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:52
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:19:20
Un-reviewed for Safety.	System	13 Nov 2020 16:28:26
DataPoint Un-verified.	System	13 Nov 2020 16:28:26
User entered 'Timothy'	System	13 Nov 2020 16:28:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:46
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered 'Mark'	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Un-reviewed for Safety.	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
User entered 'Timothy' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Mark'	System	05 Nov 2020 19:04:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Hutchens'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:19:20
Un-reviewed for Safety.	System	13 Nov 2020 16:28:26
DataPoint Un-verified.	System	13 Nov 2020 16:28:26
User entered 'Vachris'	System	13 Nov 2020 16:28:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:48
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered 'Hutchens'	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Un-reviewed for Safety.	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
User entered 'Vachris' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Hutchens'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:50
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered '3200 Red River, Suite 301'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:52
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'Austin'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:53
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'Texas'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:55
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered '78705'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'US'	System	05 Nov 2020 19:05:11

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '7'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '6'	System	21 Dec 2020 15:33:29
User entered '5'	System	23 Nov 2020 20:46:58
User entered '4'	System	17 Nov 2020 13:19:30
User entered '3'	System	13 Nov 2020 16:28:26
User entered '2'	System	09 Nov 2020 14:01:16
User entered '1'	System	05 Nov 2020 19:05:11

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'USA-US211-2020-MRNA-1273-P301000004'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Yes (Y)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Yes (Y)'	System	05 Nov 2020 19:04:46

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

FDA-CBER-2022-1614-3512231

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Mark'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:52
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:19:20
Un-reviewed for Safety.	System	13 Nov 2020 16:28:26
DataPoint Un-verified.	System	13 Nov 2020 16:28:26
User entered 'Timothy'	System	13 Nov 2020 16:28:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:46
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered 'Mark'	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Un-reviewed for Safety.	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
User entered 'Timothy' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Mark'	System	05 Nov 2020 19:04:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Hutchens'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:19:20
Un-reviewed for Safety.	System	13 Nov 2020 16:28:26
DataPoint Un-verified.	System	13 Nov 2020 16:28:26
User entered 'Vachris'	System	13 Nov 2020 16:28:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:48
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered 'Hutchens'	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Un-reviewed for Safety.	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
User entered 'Vachris' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Hutchens'	System	05 Nov 2020 19:04:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:50
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered '3200 Red River, Suite 301'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

FDA-CBER-2022-1614-3512236

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:52
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'Austin'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:53
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'Texas'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:55
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered '78705'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'US'	System	05 Nov 2020 19:05:11

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '7'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '6'	System	21 Dec 2020 15:33:29
User entered '5'	System	23 Nov 2020 20:46:58
User entered '4'	System	17 Nov 2020 13:19:30
User entered '3'	System	13 Nov 2020 16:28:26
User entered '2'	System	09 Nov 2020 14:01:16
User entered '1'	System	05 Nov 2020 19:05:11

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form (1)
Generated On: 10 Jun 2021 10:20:52
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:50
User entered '05/Nov/2020 14:05'	System	05 Nov 2020 19:05:11

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:20:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:50
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 19:05:11

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'USA-US211-2020-MRNA-1273-P301000004'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Yes (Y)'	System	05 Nov 2020 19:04:46

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Yes (Y)'	System	05 Nov 2020 19:04:46

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Mark'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:52
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:19:20
Un-reviewed for Safety.	System	13 Nov 2020 16:28:26
DataPoint Un-verified.	System	13 Nov 2020 16:28:26
User entered 'Timothy'	System	13 Nov 2020 16:28:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:46
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered 'Mark'	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Un-reviewed for Safety.	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
User entered 'Timothy' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Mark'	System	05 Nov 2020 19:04:46

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Hutchens'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:19:20
Un-reviewed for Safety.	System	13 Nov 2020 16:28:26
DataPoint Un-verified.	System	13 Nov 2020 16:28:26
User entered 'Vachris'	System	13 Nov 2020 16:28:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:48
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered 'Hutchens'	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Un-reviewed for Safety.	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
User entered 'Vachris' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Hutchens'	System	05 Nov 2020 19:04:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:50
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered '3200 Red River, Suite 301'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

FDA-CBER-2022-1614-3512254

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:52
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'Austin'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:53
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'Texas'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

FDA-CBER-2022-1614-3512256

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:55
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered '78705'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

FDA-CBER-2022-1614-3512257

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'US'	System	05 Nov 2020 19:05:11

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '7'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '6'	System	21 Dec 2020 15:33:29
User entered '5'	System	23 Nov 2020 20:46:58
User entered '4'	System	17 Nov 2020 13:19:30
User entered '3'	System	13 Nov 2020 16:28:26
User entered '2'	System	09 Nov 2020 14:01:16
User entered '1'	System	05 Nov 2020 19:05:11

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:20:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:19:00
User entered '09/Nov/2020 14:01'	System	09 Nov 2020 14:01:16

Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form (2)
Generated On: 10 Jun 2021 10:20:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:00
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 14:01:16

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'USA-US211-2020-MRNA-1273-P301000004'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Yes (Y)'	System	05 Nov 2020 19:04:46

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Yes (Y)'	System	05 Nov 2020 19:04:46

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Mark'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:52
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:19:20
Un-reviewed for Safety.	System	13 Nov 2020 16:28:26
DataPoint Un-verified.	System	13 Nov 2020 16:28:26
User entered 'Timothy'	System	13 Nov 2020 16:28:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:46
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered 'Mark'	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Un-reviewed for Safety.	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
User entered 'Timothy' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Mark'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Hutchens'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:19:20
Un-reviewed for Safety.	System	13 Nov 2020 16:28:26
DataPoint Un-verified.	System	13 Nov 2020 16:28:26
User entered 'Vachris'	System	13 Nov 2020 16:28:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:48
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered 'Hutchens'	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Un-reviewed for Safety.	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
User entered 'Vachris' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Hutchens'	System	05 Nov 2020 19:04:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:50
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered '3200 Red River, Suite 301'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:52
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'Austin'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:53
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'Texas'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

FDA-CBER-2022-1614-3512274

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:55
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered '78705'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'US'	System	05 Nov 2020 19:05:11

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '7'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '6'	System	21 Dec 2020 15:33:29
User entered '5'	System	23 Nov 2020 20:46:58
User entered '4'	System	17 Nov 2020 13:19:30
User entered '3'	System	13 Nov 2020 16:28:26
User entered '2'	System	09 Nov 2020 14:01:16
User entered '1'	System	05 Nov 2020 19:05:11

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:20:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:32:15
User entered '13/Nov/2020 16:28'	System	13 Nov 2020 16:28:26

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:20:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:32:15
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:19:20
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 16:28:26

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'USA-US211-2020-MRNA-1273-P301000004'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Yes (Y)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Yes (Y)'	System	05 Nov 2020 19:04:46

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Mark'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:52
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:19:20
Un-reviewed for Safety.	System	13 Nov 2020 16:28:26
DataPoint Un-verified.	System	13 Nov 2020 16:28:26
User entered 'Timothy'	System	13 Nov 2020 16:28:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:46
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered 'Mark'	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Un-reviewed for Safety.	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
User entered 'Timothy' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Mark'	System	05 Nov 2020 19:04:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Hutchens'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:19:20
Un-reviewed for Safety.	System	13 Nov 2020 16:28:26
DataPoint Un-verified.	System	13 Nov 2020 16:28:26
User entered 'Vachris'	System	13 Nov 2020 16:28:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:48
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered 'Hutchens'	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Un-reviewed for Safety.	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
User entered 'Vachris' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Hutchens'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:50
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered '3200 Red River, Suite 301'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:52
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'Austin'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:53
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'Texas'	Tina Rountree (b) (4)	06 Nov 2020 03:09:16

FDA-CBER-2022-1614-3512292

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:55
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered '78705'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'US'	System	05 Nov 2020 19:05:11

FDA-CBER-2022-1614-3512294

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '7'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '6'	System	21 Dec 2020 15:33:29
User entered '5'	System	23 Nov 2020 20:46:58
User entered '4'	System	17 Nov 2020 13:19:30
User entered '3'	System	13 Nov 2020 16:28:26
User entered '2'	System	09 Nov 2020 14:01:16
User entered '1'	System	05 Nov 2020 19:05:11

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:20:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:32:13
User entered '17/Nov/2020 08:19'	System	17 Nov 2020 13:19:30

Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form (4)
Generated On: 10 Jun 2021 10:20:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:46:44
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:32:13
User entered '1'	(b) (4), (b) (6)	17 Nov 2020 13:19:30

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'USA-US211-2020-MRNA-1273-P301000004'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Yes (Y)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Yes (Y)'	System	05 Nov 2020 19:04:46

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

FDA-CBER-2022-1614-3512303

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Mark'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:52
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:19:20
Un-reviewed for Safety.	System	13 Nov 2020 16:28:26
DataPoint Un-verified.	System	13 Nov 2020 16:28:26
User entered 'Timothy'	System	13 Nov 2020 16:28:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:46
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered 'Mark'	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Un-reviewed for Safety.	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
User entered 'Timothy' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Mark'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Hutchens'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:19:20
Un-reviewed for Safety.	System	13 Nov 2020 16:28:26
DataPoint Un-verified.	System	13 Nov 2020 16:28:26
User entered 'Vachris'	System	13 Nov 2020 16:28:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:48
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered 'Hutchens'	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Un-reviewed for Safety.	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
User entered 'Vachris' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Hutchens'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:50
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered '3200 Red River, Suite 301'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:52
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'Austin'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:53
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'Texas'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:55
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered '78705'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'US'	System	05 Nov 2020 19:05:11

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '7'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '6'	System	21 Dec 2020 15:33:29
User entered '5'	System	23 Nov 2020 20:46:58
User entered '4'	System	17 Nov 2020 13:19:30
User entered '3'	System	13 Nov 2020 16:28:26
User entered '2'	System	09 Nov 2020 14:01:16
User entered '1'	System	05 Nov 2020 19:05:11

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:20:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:17:26
User entered '23/Nov/2020 15:46'	System	23 Nov 2020 20:46:58

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:20:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:33:34
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:17:26
User entered '1'	(b) (4), (b) (6)	23 Nov 2020 20:46:58

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'USA-US211-2020-MRNA-1273-P301000004'	System	05 Nov 2020 19:04:46

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Yes (Y)'	System	05 Nov 2020 19:04:46

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

FDA-CBER-2022-1614-3512319

Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Yes (Y)'	System	05 Nov 2020 19:04:46

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

FDA-CBER-2022-1614-3512321

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Mark'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:52
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:19:20
Un-reviewed for Safety.	System	13 Nov 2020 16:28:26
DataPoint Un-verified.	System	13 Nov 2020 16:28:26
User entered 'Timothy'	System	13 Nov 2020 16:28:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:46
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered 'Mark'	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Un-reviewed for Safety.	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
User entered 'Timothy' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Mark'	System	05 Nov 2020 19:04:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Hutchens'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:19:20
Un-reviewed for Safety.	System	13 Nov 2020 16:28:26
DataPoint Un-verified.	System	13 Nov 2020 16:28:26
User entered 'Vachris'	System	13 Nov 2020 16:28:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:48
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered 'Hutchens'	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Un-reviewed for Safety.	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
User entered 'Vachris' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Hutchens'	System	05 Nov 2020 19:04:46

FDA-CBER-2022-1614-3512325

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:50
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered '3200 Red River, Suite 301'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:52
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'Austin'	Tina Rountree (b) (4)	06 Nov 2020 03:09:16
	(b) (4)	

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:53
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'Texas'	Tina Rountree (b) (4)	06 Nov 2020 03:09:16
	(b) (4)	

FDA-CBER-2022-1614-3512328

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:55
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered '78705'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'US'	System	05 Nov 2020 19:05:11

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '7'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '6'	System	21 Dec 2020 15:33:29
User entered '5'	System	23 Nov 2020 20:46:58
User entered '4'	System	17 Nov 2020 13:19:30
User entered '3'	System	13 Nov 2020 16:28:26
User entered '2'	System	09 Nov 2020 14:01:16
User entered '1'	System	05 Nov 2020 19:05:11

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:20:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 23:16:55
User entered '21/Dec/2020 10:33'	System	21 Dec 2020 15:33:29

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:20:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 23:16:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:33:34
User entered '1'	(b) (4), (b) (6)	21 Dec 2020 15:33:29

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'USA-US211-2020-MRNA-1273-P301000004'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Yes (Y)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Yes (Y)'	System	05 Nov 2020 19:04:46

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 19:21:53
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'No (N)'	System	05 Nov 2020 19:04:46

FDA-CBER-2022-1614-3512341

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Mark'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:52
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:19:20
Un-reviewed for Safety.	System	13 Nov 2020 16:28:26
DataPoint Un-verified.	System	13 Nov 2020 16:28:26
User entered 'Timothy'	System	13 Nov 2020 16:28:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:46
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered 'Mark'	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Un-reviewed for Safety.	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
User entered 'Timothy' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Mark'	System	05 Nov 2020 19:04:46

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Hutchens'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:38:57
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:19:20
Un-reviewed for Safety.	System	13 Nov 2020 16:28:26
DataPoint Un-verified.	System	13 Nov 2020 16:28:26
User entered 'Vachris'	System	13 Nov 2020 16:28:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:48
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered 'Hutchens'	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
Un-reviewed for Safety.	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
User entered 'Vachris' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 19:05:06
User entered 'Hutchens'	System	05 Nov 2020 19:04:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:50
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered '3200 Red River, Suite 301'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

FDA-CBER-2022-1614-3512344

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:52
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'Austin'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

FDA-CBER-2022-1614-3512345

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:53
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'Texas'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

FDA-CBER-2022-1614-3512346

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 16:28:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:18:55
Un-reviewed for Safety.	System	09 Nov 2020 14:01:16
DataPoint Un-verified.	System	09 Nov 2020 14:01:16
User entered empty.	System	09 Nov 2020 14:01:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered '78705'	Tina Rountree (b) (4) (b) (4)	06 Nov 2020 03:09:16

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:01:04
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 19:21:53
User entered 'US'	System	05 Nov 2020 19:05:11

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User entered '7'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '6'	System	21 Dec 2020 15:33:29
User entered '5'	System	23 Nov 2020 20:46:58
User entered '4'	System	17 Nov 2020 13:19:30
User entered '3'	System	13 Nov 2020 16:28:26
User entered '2'	System	09 Nov 2020 14:01:16
User entered '1'	System	05 Nov 2020 19:05:11

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:20:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:35
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
User entered '25/Mar/2021 10:05'	System	25 Mar 2021 17:05:54

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:20:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:35
User signature succeeded.	Mark Hutchens (b) (4)	25 Mar 2021 17:49:46
User entered '1'	(b) (4), (b) (6)	25 Mar 2021 17:05:54

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'USA-US211-2020-MRNA-1273-P301000007'	System	06 Dec 2020 17:44:59

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'Yes (Y)'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'No (N)'	System	06 Dec 2020 17:44:59

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'No (N)'	System	06 Dec 2020 17:44:59

Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'Yes (Y)'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'No (N)'	System	06 Dec 2020 17:44:59

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'No (N)'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'No (N)'	System	06 Dec 2020 17:44:59

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:40
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Mark'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'Timothy'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:40
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Hutchens'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'Vachris'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:18:10
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:42
User entered 'US'	System	06 Dec 2020 17:45:30

PRODUCTION RELEASE (v12.003
EAB) (1725)

1248 of 1303

FDA-CBER-2022-1614-3512366

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '3'	System	19 Jan 2021 13:37:03
User entered '2'	System	23 Dec 2020 13:18:34
User entered '1'	System	06 Dec 2020 17:45:30

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'USA-US211-2020-MRNA-1273-P301000007'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'Yes (Y)'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'No (N)'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'No (N)'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'Yes (Y)'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'No (N)'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'No (N)'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'No (N)'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:40
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Mark'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'Timothy'	System	06 Dec 2020 17:44:59

Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:40
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Hutchens'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'Vachris'	System	06 Dec 2020 17:44:59

Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:18:10
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:42
User entered 'US'	System	06 Dec 2020 17:45:30

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '3'	System	19 Jan 2021 13:37:03
User entered '2'	System	23 Dec 2020 13:18:34
User entered '1'	System	06 Dec 2020 17:45:30

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form (1)
Generated On: 10 Jun 2021 10:20:52
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:42
User entered '06/Dec/2020 17:45'	System	06 Dec 2020 17:45:30

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:20:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:18:10
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:42
User entered '1'	(b) (4), (b) (6)	06 Dec 2020 17:45:30

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'USA-US211-2020-MRNA-1273-P301000007'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'Yes (Y)'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'No (N)'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'No (N)'	System	06 Dec 2020 17:44:59

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'Yes (Y)'	System	06 Dec 2020 17:44:59

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'No (N)'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'No (N)'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'No (N)'	System	06 Dec 2020 17:44:59

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:40
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Mark'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'Timothy'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:40
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Hutchens'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'Vachris'	System	06 Dec 2020 17:44:59

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:18:10
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:42
User entered 'US'	System	06 Dec 2020 17:45:30

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '3'	System	19 Jan 2021 13:37:03
User entered '2'	System	23 Dec 2020 13:18:34
User entered '1'	System	06 Dec 2020 17:45:30

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form (2)
Generated On: 10 Jun 2021 10:20:52
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 23:16:47
User entered '23/Dec/2020 08:18'	System	23 Dec 2020 13:18:34

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:20:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:36:49
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 23:16:47
User entered '1'	(b) (4), (b) (6)	23 Dec 2020 13:18:34

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'USA-US211-2020-MRNA-1273-P301000007'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'Yes (Y)'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'No (N)'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'No (N)'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'Yes (Y)'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'No (N)'	System	06 Dec 2020 17:44:59

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:20:52

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'No (N)'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'No (N)'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:40
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Mark'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'Timothy'	System	06 Dec 2020 17:44:59

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:14:40
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	25 Mar 2021 17:49:46
Un-reviewed for Safety.	System	25 Mar 2021 17:05:54
DataPoint Un-verified.	System	25 Mar 2021 17:05:54
Signature has been broken.	System	25 Mar 2021 17:05:54
User entered 'Hutchens'	System	25 Mar 2021 17:05:54
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:42
Reviewed for Safety.	(b) (4), (b) (6)	06 Dec 2020 17:45:21
User entered 'Vachris'	System	06 Dec 2020 17:44:59

Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

FDA-CBER-2022-1614-3512414

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:18:10
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 18:42:42
User entered 'US'	System	06 Dec 2020 17:45:30

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 10:20:52

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
User entered '3'	System	19 Jan 2021 13:37:03
User entered '2'	System	23 Dec 2020 13:18:34
User entered '1'	System	06 Dec 2020 17:45:30

US3912241
Folder: SAE USA-US211-2020-MRNA-1273-P301000007
Form: Safety Report Form (3)
Generated On: 10 Jun 2021 10:20:52
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:11:52
User entered '19/Jan/2021 13:36'	System	19 Jan 2021 13:37:03

US3912241

Folder: SAE USA-US211-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:20:52

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 02:58:21
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 17:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:11:52
User entered '1'	(b) (4), (b) (6)	19 Jan 2021 13:37:03