

US3322013 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:06:51

All time stamps listed in this document are displayed in GMT

US3322013

Form: Participant Creation

Data signed: (b) (4) 26 Feb 2021 01:55:35

Generated On: 09 Jun 2021 17:06:51

Participant ID

US3322013

[mRNA-1273-P301 Completion Guidelines](#)

US3322013

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 01:56:01

Generated On: 09 Jun 2021 17:06:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Feb 2021 01:55:36

Generated On: 09 Jun 2021 17:06:51

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Feb 2021 01:55:36

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Date of Informed Consent (<i>dd MMM yyyy</i>)	17 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Feb 2021 01:55:36

Generated On: 09 Jun 2021 17:06:51

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Feb 2021 01:55:36

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Feb 2021 01:55:36

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Condition	PARTIAL RIGHT KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN JUN 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUN 2015
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JUN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Feb 2021 01:55:36

Generated On: 09 Jun 2021 17:06:51

Condition	RIGHT KNEE ARTHRITIS
Start date (dd MMM yyyy)	UN JAN 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUN 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JUN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Feb 2021 01:55:36

Generated On: 09 Jun 2021 17:06:51

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 01:56:01

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:10 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 12:10
Height (<i>xxx.x</i>)	64 in
Weight (<i>xxx.x</i>)	125 lb
BMI (<i>xxx.x</i>)	21.50106 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 01:55:36

Generated On: 09 Jun 2021 17:06:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 26 Feb 2021 01:55:36

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Date of assessment (*dd MMM yyyy*) 17 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2010

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 01:56:01

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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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 01:56:01

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- CARDIOLOGIST IN PRIVATE
PRACTICE--SEES 20 PATIENTS
DAILY IN HER OFFICE;
- ATTENDS TO PATIENTS IN
ICUS;
- ON STAFF AT MULTIPLE
MEDICAL FACILITIES;
- HAS CLOSE CONTACT WITH
>10 PEOPLE DAILY.

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
---------------------------	-------

Resides in Nursing Home or Assisted Living Facility	False
--	-------

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	True
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Specify	-ONCE A WEEK SHE GOES TO THE GROCERY STORE. -RUNS 8-10 MILES DAILY/ MARATHON RUNNER; -ATTENDS CHURCH SERVICE WEEKLY.
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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 01:56:01

Generated On: 09 Jun 2021 17:06:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Feb 2021 01:56:01

Generated On: 09 Jun 2021 17:06:51

What was the date of randomization? (dd MMM yyyy) 17 AUG 2020

What was the participant's randomization number? 105118

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Feb 2021 01:56:01

Generated On: 09 Jun 2021 17:06:51

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 01:56:01

Generated On: 09 Jun 2021 17:06:51

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	12:10 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 12:10
Temperature (xxx.x)	96.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	47 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 01:56:01

Generated On: 09 Jun 2021 17:06:51

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	15:45 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 15:45
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 01:56:01

Generated On: 09 Jun 2021 17:06:51

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.

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 01:56:01

Generated On: 09 Jun 2021 17:06:51

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) 17 AUG 2020

What was the treatment time? (00:00-23:59) 15:12 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 15:12

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 01:56:01

Generated On: 09 Jun 2021 17:06:51

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 AUG 2020

Collection time (00:00-23:59)

14:00 (24 HR)

Collection date and time (derived)

17 AUG 2020 14:00

US3322013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 01:56:01

Generated On: 09 Jun 2021 17:06:51

Collection date (dd MMM yyyy)			17 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:50	17 AUG 2020 13:50
Nasopharyngeal Swab 2	No		

US3322013

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:56:01

Generated On: 09 Jun 2021 17:06:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

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

97.6 °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 AUG 2020 15:44

PC Open Date & Time

17 AUG 2020 15:32

PC Close Date & Time

17 AUG 2020 18:02

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

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 97.8 °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	18 AUG 2020 06:08
PC Open Date & Time	17 AUG 2020 18:57
PC Close Date & Time	18 AUG 2020 11:59

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:51

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

18 AUG 2020 21:20

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:51

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

97.8 °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 AUG 2020 12:00

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:51

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

97.8 °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

20 AUG 2020 12:00

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:51

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

97.5 °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

21 AUG 2020 16:47

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:51

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

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

22 AUG 2020 12:03

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:51

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

97.9 °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

23 AUG 2020 21:39

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

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

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

None ☒

Please select one response below

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.**

None ☒

Please select one response below

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 AUG 2020 15:44

PC Open Date & Time

17 AUG 2020 15:32

PC Close Date & Time

17 AUG 2020 18:02

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

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

18 AUG 2020 06:08

PC Open Date & Time

17 AUG 2020 18:57

PC Close Date & Time

18 AUG 2020 11:59

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

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.**

None ☒

Please select one response below

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

18 AUG 2020 21:21

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

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.**

None ☒

Please select one response below

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 AUG 2020 12:00

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

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.**

None ☒

Please select one response below

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

20 AUG 2020 12:00

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

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.**

None ☒

Please select one response below

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

21 AUG 2020 16:46

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

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.**

None ☒

Please select one response below

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

22 AUG 2020 12:04

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

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.**

None ☒

Please select one response below

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

23 AUG 2020 21:39

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

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 ☐

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 15:45
PC Open Date & Time	17 AUG 2020 15:32
PC Close Date & Time	17 AUG 2020 18:02

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

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 ☐

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 06:09
PC Open Date & Time	17 AUG 2020 18:57
PC Close Date & Time	18 AUG 2020 11:59

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:51

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 ☒

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EAB) (1725)

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:51

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 21:21
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:51

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 ☒

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:51

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 12:01
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:51

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 ☒

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:51

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 12:01
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:51

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 ☒

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EAB) (1725)

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US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:51

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 16:47
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:51

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 ☒

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:51

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 12:04
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:51

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 ☒

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EAB) (1725)

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:51

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 21:40
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3322013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:55:36

Generated On: 09 Jun 2021 17:06:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322013

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:55:36

Generated On: 09 Jun 2021 17:06:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:55:36

Generated On: 09 Jun 2021 17:06:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322013

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:55:36

Generated On: 09 Jun 2021 17:06:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:55:36

Generated On: 09 Jun 2021 17:06:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322013

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:55:36

Generated On: 09 Jun 2021 17:06:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 01:56:01

Generated On: 09 Jun 2021 17:06:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 01:56:01

Generated On: 09 Jun 2021 17:06:51

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	08:45 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 08:45
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 01:56:01

Generated On: 09 Jun 2021 17:06:51

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3322013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 01:56:01

Generated On: 09 Jun 2021 17:06:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3322013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 01:56:01

Generated On: 09 Jun 2021 17:06:51

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

SUBJECT LEFT BEFORE PROCEDURES COULD BE COMPLETED

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? _____

US3322013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 01:56:01

Generated On: 09 Jun 2021 17:06:51

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3322013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 01:56:01

Generated On: 09 Jun 2021 17:06:51

Collection date (*dd MMM yyyy*)

Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3322013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:56:01

Generated On: 09 Jun 2021 17:06:51

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

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

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

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

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

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

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

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

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3322013

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:06:51

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

US3322013

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:06:51

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3322013

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:06:51

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3322013

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

Form: Visit Date

Generated On: 09 Jun 2021 17:06:51

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3322013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:06:51

Date of updated informed consent (*dd MMM yyyy*)

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

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*)

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

Continuing with mRNA-1273

US3322013

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:51

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3322013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:06:51

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00 - 23:59</i>)	<hr/>
Collection Date and Time (derived)	<hr/>

US3322013

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Feb 2021 01:55:35

Generated On: 09 Jun 2021 17:06:51

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Feb 2021 01:55:35

Generated On: 09 Jun 2021 17:06:51

AEID	USA-US060-2020-MRNA-1273-P30 1000001
Adverse event	CONVULSIVE SYNCOPE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Feb 2021 01:55:35

Generated On: 09 Jun 2021 17:06:51

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input checked="" type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

Generated On: 09 Jun 2021 17:06:51

FDA-CBER-2022-1614-0772410

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Feb 2021 01:55:35

Generated On: 09 Jun 2021 17:06:51

DONE". SHE STATED THAT
"SHE WAS A CARDIOLOGIST".
UPON ARRIVAL OF EMS,
PATIENT DECLINED
TRANSPORT. I PROVIDED
WITNESSED SIGNATURE TO
EMS FOR REFUSAL OF
TRANSPORT. REPEAT BP 135/78
AND PULSE 45. CRC (b) (6)
(b) (6) SPOKE WITH PATIENT
REGARDING HER MEDICAL
HISTORY. PATIENT REPORTED
A SIMILAR INCIDENT ABOUT 40
YEARS AGO ALSO DURING A
BLOOD DRAW. OTHERWISE,
SINCE THAT TIME THERE WERE
NO FURTHER EPISODES. THIS
MEDICAL HISTORY WAS NOT
DISCLOSED DURING HER
INITIAL SCREENING.
DISCUSSED CASE WITH DR.
VERONICA FRAGOSO (PI) AND
(b) (6).
RECOMMENDED IN AN
ABUNDANCE OF CAUTION,
THAT WE WILL HOLD VISIT 2
AND REPORT PER PROTOCOL
SAE AND ADVISEMENT FROM
SPONSOR OF HOW TO
PROCEED. ALSO
RECOMMENDED PATIENT TO
HAVE NEUROLOGY CONSULT
AND CHECK STATUS OF
MEDICAL RECORDS FROM PCP.
DISCUSSED THIS PLAN TO

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Feb 2021 01:55:35

Generated On: 09 Jun 2021 17:06:51

PATIENT, AND SHE LEFT IN THE
MIDDLE OF CONVERSATION. I
TOLD HER I WILL CONTACT
HER TOMORROW ONCE A
RECOMMENDATION WAS
RECEIVED FROM THE
SPONSOR. PATIENT WAS
UPSET AND LEFT PRIOR TO
TELLING HER THAT A
NEUROLOGY CONSULT IS
RECOMMENDED.

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

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Feb 2021 01:55:35

Generated On: 09 Jun 2021 17:06:51

AEID	
Adverse event	DIZZINESS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	17 AUG 2020
Start time (00:00-23:59)	14:00 (24 HR)
AE start date and time (derived)	17 AUG 2020 14:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 AUG 2020
End time (00:00-23:59)	14:03 (24 HR)
AE End Date and Time (derived)	17 AUG 2020 14:03
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Feb 2021 01:55:35

Generated On: 09 Jun 2021 17:06:51

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Feb 2021 01:55:36

Generated On: 09 Jun 2021 17:06:51

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

Yes ☒

No ☐

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

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Feb 2021 01:55:35

Generated On: 09 Jun 2021 17:06:51

Name of Medication MUTIVITAMINS

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

Dose per administration 1

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

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EAB) (1725)

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Feb 2021 01:55:35

Generated On: 09 Jun 2021 17:06:51

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Feb 2021 01:55:35

Generated On: 09 Jun 2021 17:06:51

Name of Medication OXYGEN

Prophylaxis Yes ☐
No ☒

Indication CONVULSIVE SYNCOPE

Dose per administration 3

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify LITERS

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

97 of 937

EAB) (1725)

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Feb 2021 01:55:35

Generated On: 09 Jun 2021 17:06:51

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		14 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Feb 2021 01:55:35

Generated On: 09 Jun 2021 17:06:51

Name of Medication AMMONIA INHALANT

Prophylaxis Yes ☐
No ☒

Indication CONVULSIVE SYNCOPE

Dose per administration .3

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify CUBIC CENTIMETER

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

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EAB) (1725)

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Feb 2021 01:55:35

Generated On: 09 Jun 2021 17:06:51

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		14 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3322013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Feb 2021 01:55:36

Generated On: 09 Jun 2021 17:06:51

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3322013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 09 Jun 2021 17:06:51

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
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US3322013

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 26 Feb 2021 01:55:36

Generated On: 09 Jun 2021 17:06:51

Date of dosing discontinuation (dd MMM yyyy) 14 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input checked="" type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

US3322013

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 26 Feb 2021 01:55:36

Generated On: 09 Jun 2021 17:06:51

Date of study discontinuation/completion (dd MMM yyyy) 14 SEP 2020

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input checked="" type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 26 Feb 2021 01:55:36

Generated On: 09 Jun 2021 17:06:51

SAEID	USA-US060-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Feb 2021 01:55:36

Generated On: 09 Jun 2021 17:06:51

SAEID	USA-US060-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/SEP/2020 14:37
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

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Feb 2021 01:55:36

Generated On: 09 Jun 2021 17:06:51

SAEID	USA-US060-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	23/SEP/2020 22:01
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

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Feb 2021 01:55:36

Generated On: 09 Jun 2021 17:06:51

SAEID	USA-US060-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	28/SEP/2020 12:41
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

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Feb 2021 01:55:36

Generated On: 09 Jun 2021 17:06:51

SAEID	USA-US060-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/OCT/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

Audit

US3322013 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

US3322013

Form: Participant Creation

Generated On: 09 Jun 2021 17:06:51

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'US3322013'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 18:54:29

US3322013

Form: Participant Creation

Generated On: 09 Jun 2021 17:06:51

[mRNA-1273-P301 Completion Guidelines](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11

US3322013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:06:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'Yes (Y)'	Frances Saubon (b) (4)	17 Aug 2020 20:20:15

US3322013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:06:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 18:54:30

US3322013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:06:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'Clinic (Clinic)'	Frances Saubon (b) (4)	17 Aug 2020 20:20:15

US3322013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:06:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'SCRN'	System	17 Aug 2020 20:20:15

US3322013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:51

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered (b) (6) 1959'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 18:54:31

US3322013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:51

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '61'	Frances Saubon (b) (4)	17 Aug 2020 20:20:34

US3322013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:51

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'YEARS'	System	17 Aug 2020 20:20:34

US3322013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:51

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered '61'	System	17 Aug 2020 20:23:12

US3322013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:51

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'Female (F)'	Frances Saubon (b) (4)	17 Aug 2020 20:20:34

US3322013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:51

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Frances Saubon (b) (4)	17 Aug 2020 20:20:34

US3322013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:51

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'I'	Frances Saubon (b) (4)	17 Aug 2020 20:20:34

US3322013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:51

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '0'	Frances Saubon (b) (4)	17 Aug 2020 20:20:34

US3322013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:51

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '0'	Frances Saubon (b) (4)	17 Aug 2020 20:20:34

US3322013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:51

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '0'	Frances Saubon (b) (4)	17 Aug 2020 20:20:34

US3322013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:51

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '0'	Frances Saubon (b) (4)	17 Aug 2020 20:20:34

US3322013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:51

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '0'	Frances Saubon (b) (4)	17 Aug 2020 20:20:34

US3322013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:51

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered empty.	Frances Saubon (b) (4)	17 Aug 2020 20:20:34

US3322013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:51

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '0'	Frances Saubon (b) (4)	17 Aug 2020 20:20:34

US3322013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:06:51

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '0'	Frances Saubon (b) (4)	17 Aug 2020 20:20:34

US3322013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:51

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '17 Aug 2020'	Frances Saubon (b) (4)	17 Aug 2020 20:23:12

US3322013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:51

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'Aug 2020'	System	17 Aug 2020 20:23:12

US3322013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:51

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered '2020'	System	17 Aug 2020 20:23:12

US3322013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:51

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'Amendment 2 (2)'	Frances Saubon (b) (4)	17 Aug 2020 20:23:12

US3322013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:51

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'Yes (Y)'	Frances Saubon (b) (4)	17 Aug 2020 20:23:12

US3322013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:51

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered empty.	Frances Saubon (b) (4)	17 Aug 2020 20:23:12

US3322013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:51

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered empty.	Frances Saubon (b) (4)	17 Aug 2020 20:23:12

US3322013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:51

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'No (N)'	Frances Saubon (b) (4)	17 Aug 2020 20:23:12

US3322013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:51

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 18:54:30

US3322013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:06:51

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'I'	System	17 Aug 2020 20:23:17

US3322013

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:06:51

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'Yes (Y)'	Frances Saubon (b) (4)	17 Aug 2020 20:23:17

US3322013

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:06:51

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'Yes (Y)'	Frances Saubon (b) (4)	17 Aug 2020 20:25:58

US3322013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee arthroplasty - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:32:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:32:20
Data point term sent to Coder	System	17 Aug 2020 20:31:25
User entered 'Partial Right Knee Replacement'	Frances Saubon (b) (4)	17 Aug 2020 20:30:42

US3322013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'UN Jun 2015' reason for change: Data Entry Error	(b) (4)	23 Sep 2020 15:41:16
User entered 'UN UNK 2015'	Blessing Felix-Okoroji (b) (4)	17 Aug 2020 20:30:42
	(b) (4)	

US3322013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '0'	Frances Saubon (b) (4)	17 Aug 2020 20:30:42

US3322013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'No (N)'	Frances Saubon (b) (4)	17 Aug 2020 20:30:42

US3322013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'UN Jun 2015' reason for change: Data Entry Error	Blessing Felix-Okoroji (b) (4)	23 Sep 2020 15:41:16
User entered 'UN UNK 2015'	Frances Saubon (b) (4)	17 Aug 2020 20:30:42

US3322013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '0'	Frances Saubon (b) (4)	17 Aug 2020 20:30:42

US3322013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:51

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'Jun 2015'	System	23 Sep 2020 15:41:16
User entered 'Jan 2015'	System	17 Aug 2020 20:30:42

US3322013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:51

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered '2015'	System	17 Aug 2020 20:30:42

US3322013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'Jun 2015'	System	23 Sep 2020 15:41:16
User entered 'Jan 2015'	System	17 Aug 2020 20:30:42

US3322013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:06:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered '2015'	System	17 Aug 2020 20:30:42

US3322013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User closed query 'Per DM CLR: Please note, Stop Date of MH = UN JUN 2015. However, start and stop date of PARTIAL RIGHT KNEE REPLACEMENT is UN UNK 2015. Review and reconcile dates so there is an appropriate match. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:37:43
Query 'Per DM CLR: Please note, Stop Date of MH = UN JUN 2015. However, start and stop date of PARTIAL RIGHT KNEE REPLACEMENT is UN UNK 2015. Review and reconcile dates so there is an appropriate match. Else, clarify. ' answered with 'Dates have been reconciled, dates for Partial Right Knee Replacement have been updated.' (Site from DM).	Blessing Felix-Okoroji (b) (4)	23 Sep 2020 15:42:58
User opened query 'Per DM CLR: Please note, Stop Date of MH = UN JUN 2015. However, start and stop date of PARTIAL RIGHT KNEE REPLACEMENT is UN UNK 2015. Review and reconcile dates so there is an appropriate match. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 08:29:37
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Knee arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:32:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:32:20
Data point term sent to Coder	System	17 Aug 2020 20:31:27
User entered 'right knee arthritis'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 20:31:13

US3322013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'UN Jan 2015'	Frances Saubon (b) (4)	17 Aug 2020 20:31:13

US3322013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '0'	Frances Saubon (b) (4)	17 Aug 2020 20:31:13

US3322013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'No (N)'	Frances Saubon (b) (4)	17 Aug 2020 20:31:13

US3322013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'UN Jun 2015'	Frances Saubon (b) (4)	17 Aug 2020 20:31:13

US3322013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '0'	Frances Saubon (b) (4)	17 Aug 2020 20:31:13

US3322013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:51

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'Jan 2015'	System	17 Aug 2020 20:31:13

US3322013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:51

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered '2015'	System	17 Aug 2020 20:31:13

US3322013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'Jun 2015'	System	17 Aug 2020 20:31:13

US3322013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:06:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered '2015'	System	17 Aug 2020 20:31:13

US3322013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:34:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:34:16
Data point term sent to Coder	System	17 Aug 2020 20:32:27
User entered 'Post-menopausal'	Frances Saubon (b) (4)	17 Aug 2020 20:31:40

US3322013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'UN UNK 2010'	Frances Saubon (b) (4)	17 Aug 2020 20:31:40

US3322013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:51

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '0'	Frances Saubon (b) (4)	17 Aug 2020 20:31:40

US3322013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'Yes (Y)'	Frances Saubon (b) (4)	17 Aug 2020 20:31:40

US3322013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:51

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered empty.	Frances Saubon (b) (4)	17 Aug 2020 20:31:40

US3322013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '0'	Frances Saubon (b) (4)	17 Aug 2020 20:31:40

US3322013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'Jan 2010'	System	17 Aug 2020 20:31:40

US3322013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:51

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered '2010'	System	17 Aug 2020 20:31:40

US3322013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered empty.	System	17 Aug 2020 20:31:40

US3322013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:06:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered empty.	System	17 Aug 2020 20:31:40

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'Yes (Y)'	Frances Saubon (b) (4)	17 Aug 2020 20:34:30

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '17 Aug 2020'	Frances Saubon (b) (4)	17 Aug 2020 20:34:30

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User closed query 'Per CDM: Please confirm if time 12:10 is AM or PM. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 22:08:50
Query 'Per CDM: Please confirm if time 12:10 is AM or PM. Thank you.' answered with 'TIME IS 12:10 PM' (Site from DM).	Blessing Felix-Okoroji (b) (4)	23 Sep 2020 18:11:27
User opened query 'Per CDM: Please confirm if time 12:10 is AM or PM. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:09:15
User entered '12:10'	Frances Saubon (b) (4)	17 Aug 2020 20:34:30

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered '17 Aug 2020 12:10'	System	17 Aug 2020 20:34:30

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '64' in	Frances Saubon (b) (4)	17 Aug 2020 20:34:30
DataPoint set to visible.	System	17 Aug 2020 20:23:17

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '125' lb	Frances Saubon (b) (4)	17 Aug 2020 20:34:30
DataPoint set to visible.	System	17 Aug 2020 20:23:17

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
Amendment Manager: User entered '21.50106'	System	17 Sep 2020 00:00:35
User entered '21.5'	System	17 Aug 2020 20:34:30
DataPoint set to visible.	System	17 Aug 2020 20:23:17

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'kg/m2'	System	17 Aug 2020 20:34:30
DataPoint set to visible.	System	17 Aug 2020 20:23:17

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered missing code ND - Not Done.	Frances Saubon (b) (4)	17 Aug 2020 20:34:30

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4)	29 Aug 2020 15:06:19
User entered 'Other (Other)'	Frances Saubon (b) (4)	17 Aug 2020 20:34:30

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User closed query 'Per DMR :Temperature is recorded as Not Done ,however "route of temperature" and "if other specify" is recorded which is not required.Kindly consider to keeping the field blank as per guidelines, else provide clarifications.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 20:05:39
Query 'Per DMR :Temperature is recorded as Not Done ,however "route of temperature" and "if other specify" is recorded which is not required.Kindly consider to keeping the field blank as per guidelines, else provide clarifications.' answered with 'Removed recorded data per query resolution. However, whenever field is left blank when entering a new entry for a new subject ID, the system triggers an automatic query indicating that the field needs data. Please clarify. Thank you. ' (Site from DM).	Frances Saubon (b) (4) (b) (4)	29 Aug 2020 15:06:23
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4) (b) (4)	29 Aug 2020 15:06:19
User opened query 'Per DMR :Temperature is recorded as Not Done ,however "route of temperature" and "if other specify" is recorded which is not required.Kindly consider to keeping the field blank as per guidelines, else provide clarifications.' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 04:00:15
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 20:34:30

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered missing code ND - Not Done.	Frances Saubon (b) (4)	17 Aug 2020 20:34:30

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'bpm'	System	17 Aug 2020 20:34:30

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered missing code ND - Not Done.	Frances Saubon (b) (4)	17 Aug 2020 20:34:30

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'breaths/min'	System	17 Aug 2020 20:34:30

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered missing code ND - Not Done.	Frances Saubon (b) (4)	17 Aug 2020 20:34:30

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'mmHg'	System	17 Aug 2020 20:34:30

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered missing code ND - Not Done.	Frances Saubon (b) (4)	17 Aug 2020 20:34:30

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'mmHg'	System	17 Aug 2020 20:34:30

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02

US3322013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:06:51

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02

US3322013

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'Yes (Y)'	Frances Saubon (b) (4)	17 Aug 2020 20:35:11

US3322013

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:51

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '17 Aug 2020'	Frances Saubon (b) (4)	17 Aug 2020 20:35:11

US3322013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '17 Aug 2020'	Frances Saubon (b) (4)	17 Aug 2020 20:36:06

US3322013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:51

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'No (N)'	Frances Saubon (b) (4)	17 Aug 2020 20:36:06

US3322013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:51

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Frances Saubon (b) (4)	17 Aug 2020 20:36:06

US3322013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:51

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered empty.	Frances Saubon (b) (4)	17 Aug 2020 20:36:06

US3322013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:51

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered empty.	Frances Saubon (b) (4)	17 Aug 2020 20:36:06

US3322013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:51

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '0'	Frances Saubon (b) (4)	17 Aug 2020 20:36:06

US3322013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:51

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'UN UNK 2010'	Frances Saubon (b) (4)	17 Aug 2020 20:36:06

US3322013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:06:51

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '0'	Frances Saubon (b) (4)	17 Aug 2020 20:36:06

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'Yes (Y)'	Frances Saubon (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'No (N)'	Frances Saubon (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

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)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'No (N)'	Frances Saubon (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

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)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'No (N)'	Frances Saubon (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'No (N)'	Frances Saubon (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

[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)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'No (N)'	Frances Saubon (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

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)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'No (N)'	Frances Saubon (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

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)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'No (N)'	Frances Saubon (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

[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)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'No (N)'	Frances Saubon (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

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)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'No (N)'	Frances Saubon (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

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)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'No (N)'	Frances Saubon (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'Yes (Y)'	Frances Saubon (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '- Cardiologist in private practice--Sees 20 patients daily in her office; - Attends to patients in ICUs; - On staff at multiple medical facilities; - Has close contact with >10 people daily.'	(b) (4) Frances Saubon (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '0'	Frances Saubon (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '0'	Frances Saubon (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

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)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '0'	Frances Saubon (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

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)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '0'	Frances Saubon (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

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)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '0'	Frances Saubon (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'I'	Frances Saubon (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'I'	Frances Saubon (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:06:51

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '-Once a week she goes to the grocery store. -Runs 8-10 miles daily/ Marathon Runner; -Attends church service weekly.'	(b) (4) Frances Saubon (b) (4) (b) (4)	17 Aug 2020 20:38:05

US3322013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User closed query 'Per GCL Lab Reconciliation: Swab: Per response "Nasal swab was not collected for Visit 2 Day 29. Please clarify."; however, Preclarus portal indicates swab was collected at illness visit on 14-SEP-2020 with accession number # 1F602386000. Kindly review the accession number and confirm the correct subject ID to which this swab sample belongs, else clarify. ' (Site from DM).		31 Mar 2021 12:51:09
Query 'Per GCL Lab Reconciliation: Swab: Per response "Nasal swab was not collected for Visit 2 Day 29. Please clarify."; however, Preclarus portal indicates swab was collected at illness visit on 14-SEP-2020 with accession number # 1F602386000. Kindly review the accession number and confirm the correct subject ID to which this swab sample belongs, else clarify. ' answered with 'v2 is not an illness visit, this patient does not have an illness visit in source, because they never saw us for an illness visit. the patient does NOT have a nasal swab in source, because patient left out facility in the middle of the visit, and did not have a nasal swab taken' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	22 Mar 2021 20:49:43
User opened query 'Per GCL Lab Reconciliation: Swab: Per response "Nasal swab was not collected for Visit 2 Day 29. Please clarify."; however, Preclarus portal indicates swab was collected at illness visit on 14-SEP-2020 with accession number # 1F602386000. Kindly review the accession number and confirm the correct subject ID to which this swab sample belongs, else clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 06:37:31
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 01:56:02
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 14SEP2020 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)	03 Nov 2020 11:40:44

US3322013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 14SEP2020 is reported underVisit 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 'Nasal swab was not collected for Visit 2 Day 29. Please clarify.' (Site from DM).	Frances Saubon (b) (4) (b) (4)	30 Oct 2020 15:34:38
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 14SEP2020 is reported underVisit 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)	30 Oct 2020 06:11:37
User entered 'Yes (Y)'	Elisa Morales (b) (4) (b) (4)	17 Aug 2020 21:04:51

US3322013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:51

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated (14SEP2020) is reported under Visit 2 Day 29 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 10:56:38
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated (14SEP2020) is reported under Visit 2 Day 29 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. ' answered with 'Per source, patient had a seizure during blood draw and samples were not collected. ' (Site from DM).	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 19:31:56
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated (14SEP2020) is reported under Visit 2 Day 29 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 09:53:12
User entered '17 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	17 Aug 2020 21:04:51

US3322013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4)	17 Aug 2020 21:04:51

US3322013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:06:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'VISIT1'	System	17 Aug 2020 21:04:51

US3322013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:45:04

US3322013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:51

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:06:30
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:06:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 19:45:04
User entered '105118' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:45:04

US3322013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:51

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 19:45:04

US3322013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:51

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)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'No (N)'	Elisa Moralez (b) (4)	17 Aug 2020 21:05:05

US3322013

Folder: Visit 1 Day 1

Form: Randomization

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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)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'No (N)'	Elisa Moralez (b) (4)	17 Aug 2020 21:05:05

US3322013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'No (N)'	Elisa Moralez (b) (4)	17 Aug 2020 21:05:05

US3322013

Folder: Visit 1 Day 1

Form: Randomization

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[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'No (N)'	Elisa Moralez (b) (4)	17 Aug 2020 21:05:05

US3322013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:51

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'No (N)'	Elisa Moralez (b) (4)	17 Aug 2020 21:05:05

US3322013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:06:51

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'No (N)'	Elisa Moralez (b) (4)	23 Sep 2020 21:48:40
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:23:07
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:42:41

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:51

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:51

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User accepted default value 'Pre-Dose (PREDOSE)'	Elisa Morales (b) (4) (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '17 Aug 2020'	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '12:10'	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered '17 Aug 2020 12:10'	System	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 06:03:30
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Frances Saubon (b) (4) (b) (4)	17 Sep 2020 13:45:39
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:00:35
User entered '96.6' F	Elisa Moralez (b) (4) (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'Oral (Oral)'	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered empty.	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '47'	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'bpm'	System	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '13'	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'breaths/min'	System	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '129'	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'mmHg'	System	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '76'	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'mmHg'	System	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:06:51

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User accepted default value 'Post-Dose (POSTDOSE)'	Elisa Morales (b) (4) (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '17 Aug 2020'	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 17:52:36
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per source' (Site from System).	Elisa Moralez (b) (4) (b) (4)	17 Aug 2020 21:07:30
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 21:07:15
User entered '15:45'	Elisa Moralez (b) (4) (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered '17 Aug 2020 15:45'	System	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '97.6' F	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'Oral (Oral)'	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered empty.	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '50'	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'bpm'	System	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '14'	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'breaths/min'	System	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '127'	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'mmHg'	System	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '87'	Elisa Moralez (b) (4)	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'mmHg'	System	17 Aug 2020 21:07:15

US3322013

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'No (N)'	Elisa Moralez (b) (4)	17 Aug 2020 21:07:39

US3322013

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:51

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered empty.	Elisa Moralez (b) (4)	17 Aug 2020 21:07:39

US3322013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'Yes (Y)'	Frances Saubon (b) (4)	17 Aug 2020 20:24:22

US3322013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:51

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered empty.	Frances Saubon (b) (4)	17 Aug 2020 20:24:22

US3322013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:51

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)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered empty.	Frances Saubon (b) (4)	17 Aug 2020 20:24:22

US3322013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:51

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 20:24:22

US3322013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '17 Aug 2020'	Frances Saubon (b) (4)	17 Aug 2020 20:24:22

US3322013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:51

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '15:12'	Frances Saubon (b) (4)	17 Aug 2020 20:24:22

US3322013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:51

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered '17 Aug 2020 15:12'	System	17 Aug 2020 20:24:22

US3322013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:51

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'Left Arm (LEFT ARM)'	Frances Saubon (b) (4)	17 Aug 2020 20:24:22

US3322013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:51

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'ONCE'	System	17 Aug 2020 20:24:22

US3322013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:06:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 20:24:22

US3322013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	17 Aug 2020 21:08:36

US3322013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '17 Aug 2020'	Elisa Moralez (b) (4)	17 Aug 2020 21:08:36

US3322013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '14:00'	Elisa Moralez (b) (4)	17 Aug 2020 21:08:36

US3322013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered '17 Aug 2020 14:00'	System	17 Aug 2020 21:08:36

US3322013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:06:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '17 Aug 2020'	Elisa Moralez (b) (4)	17 Aug 2020 21:08:51

US3322013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Elisa Moralez (b) (4) (b) (4)	17 Aug 2020 21:08:51

US3322013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	17 Aug 2020 21:08:51

US3322013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered '13:50'	Elisa Moralez (b) (4)	17 Aug 2020 21:08:51

US3322013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:51

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered '17 Aug 2020 13:50'	System	17 Aug 2020 21:08:51

US3322013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Elisa Morales (b) (4) (b) (4)	17 Aug 2020 21:08:51

US3322013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'No (N)'	Elisa Moralez (b) (4)	17 Aug 2020 21:08:51

US3322013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered empty.	Elisa Moralez (b) (4)	17 Aug 2020 21:08:51

US3322013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered empty.	System	17 Aug 2020 21:08:51

US3322013

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:06:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	17 Aug 2020 21:08:55

US3322013

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:06:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'I'	System	17 Aug 2020 21:08:55

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-17T15:43:55', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '288bab06-09f4-40e4-806a-eb14412ef7ec' User entered 'Yes (Y)'	System	17 Aug 2020 20:44:15
	System	17 Aug 2020 20:44:15

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-17T15:44:03', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '288bab06-09f4-40e4-806a-eb14412ef7ec' User entered '97.6'	System	17 Aug 2020 20:44:15
	System	17 Aug 2020 20:44:15

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-17T15:44:06', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '288bab06-09f4-40e4-806a-eb14412ef7ec'	System	17 Aug 2020 20:44:15
User entered 'No (N)'	System	17 Aug 2020 20:44:15

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-17T15:44:12', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '288bab06-09f4-40e4-806a-eb14412ef7ec' User entered '17 Aug 2020 15:44'	System	17 Aug 2020 20:44:15
	System	17 Aug 2020 20:44:15

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '17 Aug 2020 15:32'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '17 Aug 2020 18:02'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T06:07:46', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '791df29c-b7cd-48ae-9fa7-48bdd2e509fe' User entered 'Yes (Y)'	System	18 Aug 2020 11:08:27
	System	18 Aug 2020 11:08:27

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T06:08:07', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '791df29c-b7cd-48ae-9fa7-48bdd2e509fe' User entered '97.8'	System	18 Aug 2020 11:08:27
	System	18 Aug 2020 11:08:27

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T06:08:12', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '791df29c-b7cd-48ae-9fa7-48bdd2e509fe' User entered 'No (N)'	System	18 Aug 2020 11:08:27
	System	18 Aug 2020 11:08:27

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T06:08:24', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '791df29c-b7cd-48ae-9fa7-48bdd2e509fe' User entered '18 Aug 2020 06:08'	System	18 Aug 2020 11:08:27
	System	18 Aug 2020 11:08:27

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '17 Aug 2020 18:57'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 2'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T21:20:37', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'afc55843-69e0-4858-a2de-922355dbdcbb' User entered 'Yes (Y)'	System	19 Aug 2020 02:20:59
	System	19 Aug 2020 02:20:59

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T21:20:46', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'afc55843-69e0-4858-a2de-922355dbdcbb' User entered '97.7'	System	19 Aug 2020 02:20:59
	System	19 Aug 2020 02:20:59

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T21:20:50', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'afc55843-69e0-4858-a2de-922355dbdcbb' User entered 'No (N)'	System	19 Aug 2020 02:20:59
	System	19 Aug 2020 02:20:59

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T21:20:58', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'afc55843-69e0-4858-a2de-922355dbdcbb' User entered '18 Aug 2020 21:20'	System	19 Aug 2020 02:20:59
	System	19 Aug 2020 02:20:59

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 3'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-19T12:00:32', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '8f2d4a62-d683-4e8c-9cab-5bce45365d96'	System	19 Aug 2020 17:00:49
User entered 'Yes (Y)'	System	19 Aug 2020 17:00:49

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-19T12:00:39', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '8f2d4a62-d683-4e8c-9cab-5bce45365d96' User entered '97.8'	System	19 Aug 2020 17:00:49
	System	19 Aug 2020 17:00:49

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-19T12:00:42', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '8f2d4a62-d683-4e8c-9cab-5bce45365d96'	System	19 Aug 2020 17:00:49
User entered 'No (N)'	System	19 Aug 2020 17:00:49

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-19T12:00:45', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '8f2d4a62-d683-4e8c-9cab-5bce45365d96'	System	19 Aug 2020 17:00:49
User entered '19 Aug 2020 12:00'	System	19 Aug 2020 17:00:49

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 4'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-20T12:00:27', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '4cd5b25a-5675-49a7-a8cf-6402f165a1c2' User entered 'Yes (Y)'	System	20 Aug 2020 17:00:52
	System	20 Aug 2020 17:00:52

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-20T12:00:37', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '4cd5b25a-5675-49a7-a8cf-6402f165a1c2' User entered '97.8'	System	20 Aug 2020 17:00:52
	System	20 Aug 2020 17:00:52

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-20T12:00:40', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '4cd5b25a-5675-49a7-a8cf-6402f165a1c2'	System	20 Aug 2020 17:00:52
User entered 'No (N)'	System	20 Aug 2020 17:00:52

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-20T12:00:44', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '4cd5b25a-5675-49a7-a8cf-6402f165a1c2'	System	20 Aug 2020 17:00:52
User entered '20 Aug 2020 12:00'	System	20 Aug 2020 17:00:52

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 5'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-21T16:47:04', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'b72104e4-95d5-48e4-a542-0fc403077c78'	System	21 Aug 2020 21:47:18
User entered 'Yes (Y)'	System	21 Aug 2020 21:47:18

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-21T16:47:10', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'b72104e4-95d5-48e4-a542-0fc403077c78' User entered '97.5'	System	21 Aug 2020 21:47:18
	System	21 Aug 2020 21:47:18

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-21T16:47:13', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'b72104e4-95d5-48e4-a542-0fc403077c78'	System	21 Aug 2020 21:47:18
User entered 'No (N)'	System	21 Aug 2020 21:47:18

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-21T16:47:17', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'b72104e4-95d5-48e4-a542-0fc403077c78'	System	21 Aug 2020 21:47:18
User entered '21 Aug 2020 16:47'	System	21 Aug 2020 21:47:18

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 6'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-22T12:03:39', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '9ddaa284-1cac-47a6-bac6-8a2a801958e5' User entered 'Yes (Y)'	System	22 Aug 2020 17:03:54
	System	22 Aug 2020 17:03:54

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-22T12:03:48', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '9ddaa284-1cac-47a6-bac6-8a2a801958e5' User entered '97.7'	System	22 Aug 2020 17:03:54
	System	22 Aug 2020 17:03:54

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-22T12:03:50', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '9ddaa284-1cac-47a6-bac6-8a2a801958e5' User entered 'No (N)'	System	22 Aug 2020 17:03:54
	System	22 Aug 2020 17:03:54

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-22T12:03:53', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '9ddaa284-1cac-47a6-bac6-8a2a801958e5' User entered '22 Aug 2020 12:03'	System	22 Aug 2020 17:03:54
	System	22 Aug 2020 17:03:54

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 7'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-23T21:39:18', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'f7286740-5354-48ea-b3da-f4268725f41b' User entered 'Yes (Y)'	System	24 Aug 2020 02:39:34
	System	24 Aug 2020 02:39:34

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-23T21:39:27', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'f7286740-5354-48ea-b3da-f4268725f41b' User entered '97.9'	System	24 Aug 2020 02:39:34
	System	24 Aug 2020 02:39:34

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-23T21:39:29', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'f7286740-5354-48ea-b3da-f4268725f41b' User entered 'No (N)'	System	24 Aug 2020 02:39:34
	System	24 Aug 2020 02:39:34

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-23T21:39:33', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'f7286740-5354-48ea-b3da-f4268725f41b' User entered '23 Aug 2020 21:39'	System	24 Aug 2020 02:39:34
	System	24 Aug 2020 02:39:34

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-17T15:44:21', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '3cfc7ae3-f6be-46f6-8329-2499729a4c75'	System	17 Aug 2020 20:44:38
User entered 'None (1)'	System	17 Aug 2020 20:44:38

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-17T15:44:26', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '3cfc7ae3-f6be-46f6-8329-2499729a4c75'	System	17 Aug 2020 20:44:38
User entered 'No (N)'	System	17 Aug 2020 20:44:38

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-17T15:44:28', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '3cfc7ae3-f6be-46f6-8329-2499729a4c75'	System	17 Aug 2020 20:44:38
User entered 'No (N)'	System	17 Aug 2020 20:44:38

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-17T15:44:32', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '3cfc7ae3-f6be-46f6-8329-2499729a4c75'	System	17 Aug 2020 20:44:38
User entered 'None (1)'	System	17 Aug 2020 20:44:38

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-17T15:44:37', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '3cfc7ae3-f6be-46f6-8329-2499729a4c75' User entered '17 Aug 2020 15:44'	System	17 Aug 2020 20:44:38
	System	17 Aug 2020 20:44:38

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '17 Aug 2020 15:32'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '17 Aug 2020 18:02'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T06:08:30', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'ff6e13e8-0e9a-47d3-bd14-e0c6b8e9db56'	System	18 Aug 2020 11:08:49
User entered 'None (1)'	System	18 Aug 2020 11:08:49

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T06:08:34', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'ff6e13e8-0e9a-47d3-bd14-e0c6b8e9db56'	System	18 Aug 2020 11:08:49
User entered 'No (N)'	System	18 Aug 2020 11:08:49

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T06:08:37', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'ff6e13e8-0e9a-47d3-bd14-e0c6b8e9db56' User entered 'No (N)'	System	18 Aug 2020 11:08:49
	System	18 Aug 2020 11:08:49

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T06:08:42', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'ff6e13e8-0e9a-47d3-bd14-e0c6b8e9db56'	System	18 Aug 2020 11:08:49
User entered 'None (1)'	System	18 Aug 2020 11:08:49

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T06:08:47', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'ff6e13e8-0e9a-47d3-bd14-e0c6b8e9db56' User entered '18 Aug 2020 06:08'	System	18 Aug 2020 11:08:49
	System	18 Aug 2020 11:08:49

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '17 Aug 2020 18:57'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 2'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T21:21:02', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '03606639-3acc-480b-bf2f-bfcf29fa1100' User entered 'None (1)'	System	19 Aug 2020 02:21:15
	System	19 Aug 2020 02:21:15

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T21:21:06', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '03606639-3acc-480b-bf2f-bfcf29fa1100'	System	19 Aug 2020 02:21:15
User entered 'No (N)'	System	19 Aug 2020 02:21:15

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T21:21:08', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '03606639-3acc-480b-bf2f-bfcf29fa1100' User entered 'No (N)'	System	19 Aug 2020 02:21:15
	System	19 Aug 2020 02:21:15

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T21:21:10', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '03606639-3acc-480b-bf2f-bfcf29fa1100'	System	19 Aug 2020 02:21:15
User entered 'None (1)'	System	19 Aug 2020 02:21:15

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T21:21:13', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '03606639-3acc-480b-bf2f-bfcf29fa1100'	System	19 Aug 2020 02:21:15
User entered '18 Aug 2020 21:21'	System	19 Aug 2020 02:21:15

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 3'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-19T12:00:49', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '21e05e07-a57d-445c-803e-bd1d6671681e' User entered 'None (1)'	System	19 Aug 2020 17:01:02
	System	19 Aug 2020 17:01:02

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-19T12:00:51', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '21e05e07-a57d-445c-803e-bd1d6671681e' User entered 'No (N)'	System	19 Aug 2020 17:01:02
	System	19 Aug 2020 17:01:02

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-19T12:00:53', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '21e05e07-a57d-445c-803e-bd1d6671681e' User entered 'No (N)'	System	19 Aug 2020 17:01:02
	System	19 Aug 2020 17:01:02

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-19T12:00:56', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '21e05e07-a57d-445c-803e-bd1d6671681e' User entered 'None (1)'	System	19 Aug 2020 17:01:02
	System	19 Aug 2020 17:01:02

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-19T12:00:58', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '21e05e07-a57d-445c-803e-bd1d6671681e' User entered '19 Aug 2020 12:00'	System	19 Aug 2020 17:01:02
	System	19 Aug 2020 17:01:02

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 4'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-20T12:00:47', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '3ceea201-e23f-4543-93fc-af44866ca5ea' User entered 'None (1)'	System	20 Aug 2020 17:01:19
	System	20 Aug 2020 17:01:19

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-20T12:00:49', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '3ceea201-e23f-4543-93fc-af44866ca5ea' User entered 'No (N)'	System	20 Aug 2020 17:01:19
	System	20 Aug 2020 17:01:19

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-20T12:00:52', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '3ceea201-e23f-4543-93fc-af44866ca5ea' User entered 'No (N)'	System	20 Aug 2020 17:01:19
	System	20 Aug 2020 17:01:19

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-20T12:00:54', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '3ceea201-e23f-4543-93fc-af44866ca5ea' User entered 'None (1)'	System	20 Aug 2020 17:01:19
	System	20 Aug 2020 17:01:19

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-20T12:00:58', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '3ceea201-e23f-4543-93fc-af44866ca5ea' User entered '20 Aug 2020 12:00'	System	20 Aug 2020 17:01:19
	System	20 Aug 2020 17:01:19

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 5'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-21T16:46:45', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '3a14e613-d88c-450e-978f-c56b45710567' User entered 'None (1)'	System	21 Aug 2020 21:47:01
	System	21 Aug 2020 21:47:01

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-21T16:46:48', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '3a14e613-d88c-450e-978f-c56b45710567' User entered 'No (N)'	System	21 Aug 2020 21:47:01
	System	21 Aug 2020 21:47:01

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-21T16:46:51', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '3a14e613-d88c-450e-978f-c56b45710567' User entered 'No (N)'	System	21 Aug 2020 21:47:01
	System	21 Aug 2020 21:47:01

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-21T16:46:53', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '3a14e613-d88c-450e-978f-c56b45710567' User entered 'None (1)'	System	21 Aug 2020 21:47:01
	System	21 Aug 2020 21:47:01

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-21T16:46:56', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '3a14e613-d88c-450e-978f-c56b45710567' User entered '21 Aug 2020 16:46'	System	21 Aug 2020 21:47:01
	System	21 Aug 2020 21:47:01

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 6'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-22T12:03:56', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '4e8c347c-d24e-431b-bf9a-ef2ed33c7d42'	System	22 Aug 2020 17:04:06
User entered 'None (1)'	System	22 Aug 2020 17:04:06

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-22T12:03:59', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '4e8c347c-d24e-431b-bf9a-ef2ed33c7d42'	System	22 Aug 2020 17:04:06
User entered 'No (N)'	System	22 Aug 2020 17:04:06

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-22T12:04:00', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '4e8c347c-d24e-431b-bf9a-ef2ed33c7d42'	System	22 Aug 2020 17:04:06
User entered 'No (N)'	System	22 Aug 2020 17:04:06

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-22T12:04:02', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '4e8c347c-d24e-431b-bf9a-ef2ed33c7d42'	System	22 Aug 2020 17:04:06
User entered 'None (1)'	System	22 Aug 2020 17:04:06

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-22T12:04:04', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '4e8c347c-d24e-431b-bf9a-ef2ed33c7d42'	System	22 Aug 2020 17:04:06
User entered '22 Aug 2020 12:04'	System	22 Aug 2020 17:04:06

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 7'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-23T21:39:36', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '5f25f311-e0b4-4f53-8f9c-e62dca442a00'	System	24 Aug 2020 02:39:48
User entered 'None (1)'	System	24 Aug 2020 02:39:48

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-23T21:39:38', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '5f25f311-e0b4-4f53-8f9c-e62dca442a00'	System	24 Aug 2020 02:39:48
User entered 'No (N)'	System	24 Aug 2020 02:39:48

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-23T21:39:40', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '5f25f311-e0b4-4f53-8f9c-e62dca442a00' User entered 'No (N)'	System	24 Aug 2020 02:39:48
	System	24 Aug 2020 02:39:48

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-23T21:39:42', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '5f25f311-e0b4-4f53-8f9c-e62dca442a00'	System	24 Aug 2020 02:39:48
User entered 'None (1)'	System	24 Aug 2020 02:39:48

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-23T21:39:45', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '5f25f311-e0b4-4f53-8f9c-e62dca442a00'	System	24 Aug 2020 02:39:48
User entered '23 Aug 2020 21:39'	System	24 Aug 2020 02:39:48

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-17T15:44:42', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '4c332bc0-c317-489c-8b04-ace9ef481170' User entered 'None (0)'	System	17 Aug 2020 20:45:05
	System	17 Aug 2020 20:45:05

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-17T15:44:44', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '4c332bc0-c317-489c-8b04-ace9ef481170' User entered 'None (0)'	System	17 Aug 2020 20:45:05
	System	17 Aug 2020 20:45:05

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-17T15:44:47', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '4c332bc0-c317-489c-8b04-ace9ef481170' User entered 'None (0)'	System	17 Aug 2020 20:45:05
	System	17 Aug 2020 20:45:05

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-17T15:44:49', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '4c332bc0-c317-489c-8b04-ace9ef481170' User entered 'None (0)'	System	17 Aug 2020 20:45:05
	System	17 Aug 2020 20:45:05

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-17T15:44:51', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '4c332bc0-c317-489c-8b04-ace9ef481170' User entered 'None (0)'	System	17 Aug 2020 20:45:05
	System	17 Aug 2020 20:45:05

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-17T15:44:53', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '4c332bc0-c317-489c-8b04-ace9ef481170' User entered 'None (0)'	System	17 Aug 2020 20:45:05
	System	17 Aug 2020 20:45:05

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-17T15:44:57', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '4c332bc0-c317-489c-8b04-ace9ef481170' User entered 'No (N)'	System	17 Aug 2020 20:45:05
	System	17 Aug 2020 20:45:05

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-17T15:45:01', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '4c332bc0-c317-489c-8b04-ace9ef481170' User entered '17 Aug 2020 15:45'	System	17 Aug 2020 20:45:05
	System	17 Aug 2020 20:45:05

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '17 Aug 2020 15:32'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '17 Aug 2020 18:02'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T06:08:54', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '900681fb-777a-4c15-a9c8-855653df0230' User entered 'None (0)'	System	18 Aug 2020 11:09:18
	System	18 Aug 2020 11:09:18

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T06:08:57', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '900681fb-777a-4c15-a9c8-855653df0230' User entered 'None (0)'	System	18 Aug 2020 11:09:18
	System	18 Aug 2020 11:09:18

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T06:08:59', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '900681fb-777a-4c15-a9c8-855653df0230' User entered 'None (0)'	System	18 Aug 2020 11:09:18
	System	18 Aug 2020 11:09:18

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T06:09:02', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '900681fb-777a-4c15-a9c8-855653df0230' User entered 'None (0)'	System	18 Aug 2020 11:09:18
	System	18 Aug 2020 11:09:18

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T06:09:05', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '900681fb-777a-4c15-a9c8-855653df0230' User entered 'None (0)'	System	18 Aug 2020 11:09:18
	System	18 Aug 2020 11:09:18

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T06:09:07', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '900681fb-777a-4c15-a9c8-855653df0230' User entered 'None (0)'	System	18 Aug 2020 11:09:18
	System	18 Aug 2020 11:09:18

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T06:09:11', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '900681fb-777a-4c15-a9c8-855653df0230' User entered 'No (N)'	System	18 Aug 2020 11:09:18
	System	18 Aug 2020 11:09:18

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T06:09:16', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '900681fb-777a-4c15-a9c8-855653df0230' User entered '18 Aug 2020 06:09'	System	18 Aug 2020 11:09:18
	System	18 Aug 2020 11:09:18

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '17 Aug 2020 18:57'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 2'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T21:21:18', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '2de00d48-ce39-4caf-8f67-4c5bde5a172c' User entered 'None (0)'	System	19 Aug 2020 02:21:37
	System	19 Aug 2020 02:21:37

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T21:21:20', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '2de00d48-ce39-4caf-8f67-4c5bde5a172c' User entered 'None (0)'	System	19 Aug 2020 02:21:37
	System	19 Aug 2020 02:21:37

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T21:21:21', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '2de00d48-ce39-4caf-8f67-4c5bde5a172c' User entered 'None (0)'	System	19 Aug 2020 02:21:37
	System	19 Aug 2020 02:21:37

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T21:21:24', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '2de00d48-ce39-4caf-8f67-4c5bde5a172c' User entered 'None (0)'	System	19 Aug 2020 02:21:37
	System	19 Aug 2020 02:21:37

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T21:21:26', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '2de00d48-ce39-4caf-8f67-4c5bde5a172c' User entered 'None (0)'	System	19 Aug 2020 02:21:37
	System	19 Aug 2020 02:21:37

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T21:21:28', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '2de00d48-ce39-4caf-8f67-4c5bde5a172c' User entered 'None (0)'	System	19 Aug 2020 02:21:37
	System	19 Aug 2020 02:21:37

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T21:21:32', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '2de00d48-ce39-4caf-8f67-4c5bde5a172c' User entered 'No (N)'	System	19 Aug 2020 02:21:37
	System	19 Aug 2020 02:21:37

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-18T21:21:35', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '2de00d48-ce39-4caf-8f67-4c5bde5a172c' User entered '18 Aug 2020 21:21'	System	19 Aug 2020 02:21:37
	System	19 Aug 2020 02:21:37

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 3'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-19T12:01:02', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '6a4940c5-6594-412b-abd5-6e288a54bb39' User entered 'None (0)'	System	19 Aug 2020 17:01:22
	System	19 Aug 2020 17:01:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-19T12:01:03', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '6a4940c5-6594-412b-abd5-6e288a54bb39' User entered 'None (0)'	System	19 Aug 2020 17:01:22
	System	19 Aug 2020 17:01:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-19T12:01:05', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '6a4940c5-6594-412b-abd5-6e288a54bb39' User entered 'None (0)'	System	19 Aug 2020 17:01:22
	System	19 Aug 2020 17:01:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-19T12:01:07', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '6a4940c5-6594-412b-abd5-6e288a54bb39' User entered 'None (0)'	System	19 Aug 2020 17:01:22
	System	19 Aug 2020 17:01:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-19T12:01:09', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '6a4940c5-6594-412b-abd5-6e288a54bb39' User entered 'None (0)'	System	19 Aug 2020 17:01:22
	System	19 Aug 2020 17:01:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-19T12:01:11', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '6a4940c5-6594-412b-abd5-6e288a54bb39' User entered 'None (0)'	System	19 Aug 2020 17:01:22
	System	19 Aug 2020 17:01:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-19T12:01:16', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '6a4940c5-6594-412b-abd5-6e288a54bb39' User entered 'No (N)'	System	19 Aug 2020 17:01:22
	System	19 Aug 2020 17:01:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-19T12:01:19', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '6a4940c5-6594-412b-abd5-6e288a54bb39' User entered '19 Aug 2020 12:01'	System	19 Aug 2020 17:01:22
	System	19 Aug 2020 17:01:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 4'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-20T12:01:02', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '680d883e-4345-409e-9d85-2a6aa9be6880' User entered 'None (0)'	System	20 Aug 2020 17:01:42
	System	20 Aug 2020 17:01:42

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-20T12:01:03', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '680d883e-4345-409e-9d85-2a6aa9be6880' User entered 'None (0)'	System	20 Aug 2020 17:01:42
	System	20 Aug 2020 17:01:42

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-20T12:01:05', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '680d883e-4345-409e-9d85-2a6aa9be6880' User entered 'None (0)'	System	20 Aug 2020 17:01:42
	System	20 Aug 2020 17:01:42

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-20T12:01:06', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '680d883e-4345-409e-9d85-2a6aa9be6880' User entered 'None (0)'	System	20 Aug 2020 17:01:42
	System	20 Aug 2020 17:01:42

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-20T12:01:08', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '680d883e-4345-409e-9d85-2a6aa9be6880' User entered 'None (0)'	System	20 Aug 2020 17:01:42
	System	20 Aug 2020 17:01:42

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-20T12:01:10', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '680d883e-4345-409e-9d85-2a6aa9be6880' User entered 'None (0)'	System	20 Aug 2020 17:01:42
	System	20 Aug 2020 17:01:42

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-20T12:01:13', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '680d883e-4345-409e-9d85-2a6aa9be6880' User entered 'No (N)'	System	20 Aug 2020 17:01:42
	System	20 Aug 2020 17:01:42

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-20T12:01:16', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '680d883e-4345-409e-9d85-2a6aa9be6880' User entered '20 Aug 2020 12:01'	System	20 Aug 2020 17:01:42
	System	20 Aug 2020 17:01:42

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 5'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-21T16:47:20', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'adf551fb-0b27-42d0-9d1d-4e1d572269a9' User entered 'None (0)'	System	21 Aug 2020 21:47:36
	System	21 Aug 2020 21:47:36

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-21T16:47:22', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'adf551fb-0b27-42d0-9d1d-4e1d572269a9' User entered 'None (0)'	System	21 Aug 2020 21:47:36
	System	21 Aug 2020 21:47:36

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-21T16:47:24', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'adf551fb-0b27-42d0-9d1d-4e1d572269a9' User entered 'None (0)'	System	21 Aug 2020 21:47:36
	System	21 Aug 2020 21:47:36

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-21T16:47:25', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'adf551fb-0b27-42d0-9d1d-4e1d572269a9' User entered 'None (0)'	System	21 Aug 2020 21:47:36
	System	21 Aug 2020 21:47:36

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-21T16:47:27', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'adf551fb-0b27-42d0-9d1d-4e1d572269a9' User entered 'None (0)'	System	21 Aug 2020 21:47:36
	System	21 Aug 2020 21:47:36

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-21T16:47:29', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'adf551fb-0b27-42d0-9d1d-4e1d572269a9' User entered 'None (0)'	System	21 Aug 2020 21:47:36
	System	21 Aug 2020 21:47:36

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-21T16:47:32', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'adf551fb-0b27-42d0-9d1d-4e1d572269a9' User entered 'No (N)'	System	21 Aug 2020 21:47:36
	System	21 Aug 2020 21:47:36

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-21T16:47:34', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: 'adf551fb-0b27-42d0-9d1d-4e1d572269a9' User entered '21 Aug 2020 16:47'	System	21 Aug 2020 21:47:36
	System	21 Aug 2020 21:47:36

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 6'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-22T12:04:07', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '0afa681f-c652-4fa0-8dcc-797a295802c1' User entered 'None (0)'	System	22 Aug 2020 17:04:24
	System	22 Aug 2020 17:04:24

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-22T12:04:09', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '0afa681f-c652-4fa0-8dcc-797a295802c1' User entered 'None (0)'	System	22 Aug 2020 17:04:24
	System	22 Aug 2020 17:04:24

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-22T12:04:11', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '0afa681f-c652-4fa0-8dcc-797a295802c1' User entered 'None (0)'	System	22 Aug 2020 17:04:24
	System	22 Aug 2020 17:04:24

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-22T12:04:12', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '0afa681f-c652-4fa0-8dcc-797a295802c1' User entered 'None (0)'	System	22 Aug 2020 17:04:24
	System	22 Aug 2020 17:04:24

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-22T12:04:15', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '0afa681f-c652-4fa0-8dcc-797a295802c1' User entered 'None (0)'	System	22 Aug 2020 17:04:24
	System	22 Aug 2020 17:04:24

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-22T12:04:16', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '0afa681f-c652-4fa0-8dcc-797a295802c1' User entered 'None (0)'	System	22 Aug 2020 17:04:24
	System	22 Aug 2020 17:04:24

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-22T12:04:21', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '0afa681f-c652-4fa0-8dcc-797a295802c1' User entered 'No (N)'	System	22 Aug 2020 17:04:24
	System	22 Aug 2020 17:04:24

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-22T12:04:23', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '0afa681f-c652-4fa0-8dcc-797a295802c1' User entered '22 Aug 2020 12:04'	System	22 Aug 2020 17:04:24
	System	22 Aug 2020 17:04:24

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 7'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-23T21:39:48', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '309dec41-571a-41df-b4ca-9c17f508cc87' User entered 'None (0)'	System	24 Aug 2020 02:40:05
	System	24 Aug 2020 02:40:05

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-23T21:39:50', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '309dec41-571a-41df-b4ca-9c17f508cc87' User entered 'None (0)'	System	24 Aug 2020 02:40:05
	System	24 Aug 2020 02:40:05

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-23T21:39:51', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '309dec41-571a-41df-b4ca-9c17f508cc87' User entered 'None (0)'	System	24 Aug 2020 02:40:05
	System	24 Aug 2020 02:40:05

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-23T21:39:54', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '309dec41-571a-41df-b4ca-9c17f508cc87' User entered 'None (0)'	System	24 Aug 2020 02:40:05
	System	24 Aug 2020 02:40:05

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-23T21:39:55', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '309dec41-571a-41df-b4ca-9c17f508cc87' User entered 'None (0)'	System	24 Aug 2020 02:40:05
	System	24 Aug 2020 02:40:05

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-23T21:39:57', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '309dec41-571a-41df-b4ca-9c17f508cc87' User entered 'None (0)'	System	24 Aug 2020 02:40:05
	System	24 Aug 2020 02:40:05

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:51

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 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-23T21:39:59', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '309dec41-571a-41df-b4ca-9c17f508cc87'	System	24 Aug 2020 02:40:05
User entered 'No (N)'	System	24 Aug 2020 02:40:05

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (05F15F11-9AD6-46BA-9BAB-3E8481EBA6CC)', Time: '2020-08-23T21:40:01', User OID: 'PatientReportedOutcome (US3322013)', ODM File OID: '309dec41-571a-41df-b4ca-9c17f508cc87' User entered '23 Aug 2020 21:40'	System	24 Aug 2020 02:40:05
	System	24 Aug 2020 02:40:05

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 20:24:22

US3322013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:06:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:58
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	01 Sep 2020 13:37:16

US3322013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '24 Aug 2020'	Elisa Moralez (b) (4)	01 Sep 2020 13:37:16

US3322013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	01 Sep 2020 13:37:16

US3322013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered empty.	Elisa Moralez (b) (4)	01 Sep 2020 13:37:16

US3322013

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	01 Sep 2020 13:37:19

US3322013

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'I'	System	01 Sep 2020 13:37:19

US3322013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	09 Sep 2020 00:18:28

US3322013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '01 Sep 2020' reason for change: Per Query Resolution	(b) (4)	
	Elisa Moralez (b) (4)	10 Nov 2020 14:32:23
User entered '1 Sep 2020'	(b) (4)	
	Elisa Moralez (b) (4)	09 Sep 2020 00:18:28
	(b) (4)	

US3322013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	09 Sep 2020 00:18:28

US3322013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered empty.	Elisa Moralez (b) (4)	09 Sep 2020 00:18:28

US3322013

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	09 Sep 2020 00:18:34

US3322013

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'I'	System	09 Sep 2020 00:18:34

US3322013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	11 Sep 2020 20:44:07

US3322013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	11 Sep 2020 20:44:14
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	11 Sep 2020 20:44:14
User entered '10 Sep 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4)	11 Sep 2020 20:44:14
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	11 Sep 2020 20:44:07
User entered '11 Sep 2020'	Elisa Moralez (b) (4)	11 Sep 2020 20:44:07

US3322013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	11 Sep 2020 20:44:07

US3322013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:06:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered empty.	Elisa Moralez (b) (4)	11 Sep 2020 20:44:07

US3322013

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User closed query 'Per CDM: Please complete Visit 2 Day 29 assessments, if applicable.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please complete Visit 2 Day 29 assessments, if applicable.' answered with 'Subject's visit 2 is incomplete due to SAE as recorded in AE folder. Site has had multiple unsuccessful attempts to follow up with patient. Site has proceeded to mail a certified letter. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 09:18:55
Query 'Per CDM: Please complete Visit 2 Day 29 assessments, if applicable.' answered with 'Subject's visit 2 is incomplete due to SAE as recorded in AE folder. Site has had multiple unsuccessful attempts to follow up with patient. Site has proceeded to mail a certified letter. ' (Site from DM).	Frances Saubon (b) (4)	07 Oct 2020 14:33:07
User opened query 'Per CDM: Please complete Visit 2 Day 29 assessments, if applicable.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please complete Visit 2 Day 29 assessments. Per GCL samples were collected on 14Sep2020, however; there is no record of this visit in EDC' canceled (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 01:11:51
User opened query 'Per CDM: Please complete Visit 2 Day 29 assessments. Per GCL samples were collected on 14Sep2020, however; there is no record of this visit in EDC' (Site from DM).		07 Oct 2020 01:11:35
User entered 'Yes (Y)'		06 Oct 2020 23:38:50
	Elisa Moralez (b) (4)	11 Sep 2020 20:44:18
	(b) (4)	

US3322013

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:56:02
User entered 'I'	System	11 Sep 2020 20:44:18

US3322013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4), (b) (6)	27 Dec 2020 00:43:52
User entered 'Yes (Y)'	Frances Saubon (b) (4)	11 Dec 2020 17:35:02

US3322013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4), (b) (6)	27 Dec 2020 00:43:52
User entered '14 Sep 2020'	Frances Saubon (b) (4)	11 Dec 2020 17:35:02

US3322013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:43:52
User entered 'Clinic (Clinic)'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:35:02

US3322013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:06:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered 'VISIT2'	System	11 Dec 2020 17:35:02

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User accepted default value 'Pre-Dose (PREDOSE)'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:44:24
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:44:24
User entered '14 Sep 2020'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:44:24
User entered '08:45'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered '14 Sep 2020 08:45'	System	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4), (b) (6)	27 Dec 2020 00:44:24
User entered '97.3' F	Frances Saubon (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:44:24
User entered 'Oral (Oral)'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:44:24
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:44:24
User entered '51'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered 'bpm'	System	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:44:24
User entered '16'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered 'breaths/min'	System	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:44:24
User entered '125'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered 'mmHg'	System	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:44:24
User entered '73'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:06:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered 'mmHg'	System	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User accepted default value 'Post-Dose (POSTDOSE)'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:44:24
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:44:24
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:44:24
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered empty.	System	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:44:24
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:44:24
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:44:24
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:44:24
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered empty.	System	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:44:24
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered empty.	System	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:44:24
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered empty.	System	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:44:24
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:06:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered empty.	System	11 Dec 2020 17:36:50

US3322013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:48:43
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:53:07

US3322013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:06:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4), (b) (6)	27 Dec 2020 00:48:43
User entered '14 Sep 2020'	Frances Saubon (b) (4)	11 Dec 2020 17:53:07

US3322013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:49:20
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:53:44

US3322013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:51

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:49:20
User entered 'Other (OTHER)'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:53:44

US3322013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:51

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)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:49:20
User entered 'Subject left before procedures could be completed'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:53:44

US3322013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:51

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered empty.	System	11 Dec 2020 17:53:44

US3322013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:49:20
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:53:44

US3322013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:51

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:49:20
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:53:44

US3322013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:51

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered empty.	System	11 Dec 2020 17:53:44

US3322013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:51

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:49:20
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:53:44

US3322013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:51

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint Verified.		27 Dec 2020 00:49:20
User entered empty.	System	11 Dec 2020 17:53:44

US3322013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:06:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered empty.	System	11 Dec 2020 17:53:44

US3322013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4), (b) (6)	27 Dec 2020 00:59:01
User entered 'No (N)'	Frances Saubon (b) (4)	11 Dec 2020 17:53:54

US3322013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:59:01
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:53:54

US3322013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:59:01
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:53:54

US3322013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:06:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered empty.	System	11 Dec 2020 17:53:54

US3322013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:06:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:59:07
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:54:01

US3322013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:54:01

US3322013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:59:07
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:54:01

US3322013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:59:07
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:54:01

US3322013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:06:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered empty.	System	11 Dec 2020 17:54:01

US3322013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:54:01

US3322013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:59:07
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:54:01

US3322013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:59:07
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:54:01

US3322013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:06:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered empty.	System	11 Dec 2020 17:54:01

US3322013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:56:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:59:17
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 17:54:06

US3322013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:06:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered empty.	System	11 Dec 2020 17:54:06

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 64'	System	17 Aug 2020 20:24:22

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[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)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[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)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:06:51

[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)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[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)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

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[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)	28 Apr 2021 15:17:11
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US3322013

Folder: Safety Follow Up Diary (1)

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[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)	28 Apr 2021 15:17:11
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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57
Data entry locked.	System	17 Aug 2020 20:24:22
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 20:24:22

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57
Data entry locked.	System	17 Aug 2020 20:24:22
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 71'	System	17 Aug 2020 20:24:22

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[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)
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US3322013

Folder: Safety Follow Up Diary (1)

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[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)	28 Apr 2021 15:17:11
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US3322013

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[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.](#)

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[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)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:06:51

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

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Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

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Folder: Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3322013

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

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[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)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3322013

Folder: Safety Follow Up Diary (1)

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[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)	28 Apr 2021 15:17:11
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US3322013

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[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)
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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57
Data entry locked.	System	17 Aug 2020 20:24:22
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 20:24:22

US3322013

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57
Data entry locked.	System	17 Aug 2020 20:24:22
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 20:24:22

US3322013

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 78'	System	17 Aug 2020 20:24:22

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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)
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US3322013

Folder: Safety Follow Up Diary (1)

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[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)	28 Apr 2021 15:17:11
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US3322013

Folder: Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[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)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[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)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[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)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[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)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57
Data entry locked.	System	17 Aug 2020 20:24:22
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 20:24:22

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57
Data entry locked.	System	17 Aug 2020 20:24:22
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57
Data entry locked.	System	17 Aug 2020 20:24:22
User entered 'Day 92'	System	17 Aug 2020 20:24:22

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[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)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

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)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[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)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[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)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[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)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[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)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[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)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57
Data entry locked.	System	17 Aug 2020 20:24:22
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 20:24:22

US3322013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:06:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 09:33:57
Data entry locked.	System	17 Aug 2020 20:24:22
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 20:24:22

US3322013

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:06:51

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User closed query 'Per source, AE of dizziness is reported. Please enter in EDC.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:45:57
Query 'Per source, AE of dizziness is reported. Please enter in EDC.' answered with 'entering now' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:50:25
User opened query 'Per source, AE of dizziness is reported. Please enter in EDC.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 15:58:54
DataPoint Verified.		23 Sep 2020 15:58:29
User entered 'Yes (Y)'		14 Sep 2020 22:37:27

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:02:42
Reviewed for Safety.		15 Sep 2020 18:37:10
User entered 'USA-US060-2020-mRNA-1273-P301000001'	System	15 Sep 2020 18:36:54
User entered 'New'	(b) (4), (b) (6)	15 Sep 2020 18:36:54

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:02:44
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope convulsive - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 00:24:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 00:24:55
Data point term sent to Coder	System	14 Sep 2020 22:40:34
User entered 'Convulsive syncope'	(b) (4), (b) (6)	14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:45:54
User closed query 'Please update to No, since subject was being seen for Day 29 at this time and was not brought in specifically for a new AE.' (Site from CRA).		20 Oct 2020 17:45:51
Query 'Please update to No, since subject was being seen for Day 29 at this time and was not brought in specifically for a new AE.' answered with 'done.' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:51:02
User entered 'No (N)' reason for change: Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:50:55
User opened query 'Please update to No, since subject was being seen for Day 29 at this time and was not brought in specifically for a new AE.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 16:01:15
User entered 'Yes (Y)'		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:02:46
User entered 'No (N)'		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:02:47
User entered 'No (N)'		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:02:58
User entered '14 Sep 2020'		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:02:59
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	14 Sep 2020 22:41:34
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 22:41:34
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	14 Sep 2020 22:39:53
User entered '10:20'	(b) (4), (b) (6)	14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered empty.	System	14 Sep 2020 22:41:34
User entered '14 Sep 2020 10:20'	System	14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:00
User entered 'No (N)'		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:03
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	14 Sep 2020 22:41:34
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	14 Sep 2020 22:41:34
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	14 Sep 2020 22:39:53
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:02
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	14 Sep 2020 22:41:34
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 22:41:34
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	14 Sep 2020 22:39:53
User entered '10:40'	(b) (4), (b) (6)	14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered empty.	System	14 Sep 2020 22:41:34
User entered '14 Sep 2020 10:40'	System	14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:19
User entered 'Grade 3/Severe (Grade 3/Severe)'		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:23
User entered 'Yes (Y)'		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:28
User entered '0'		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:30
User entered '0'		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:31
User entered '0'		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:33
User entered empty.		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:35
User entered empty.		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:36
User entered empty.		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	23 Sep 2020 16:03:38
User entered empty.		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:41
User entered '0'		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:43
User entered '0'		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:45
User entered 'l'		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:58
User entered 'Not Related (NOT RELATED)'		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:04:00
User entered 'Related (RELATED)'		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:40:22
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'per source "Recommended in an abundance of caution, we will hold visit 2 and report per protocol SAE and advisement from sponsor of how to proceed." So, per PI, patient was rescheduled to another day after followups with PCP, neurologist, and medical record review.' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 17:49:43
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 13:10:47
DataPoint Verified.		23 Sep 2020 16:04:05
User entered 'Dose Delayed (DOSE DELAYED)'		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:57
User entered '0'		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:57
User entered '1' reason for change: New Information	Elisa Moralez (b) (4)	25 Sep 2020 17:41:30
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:57
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).		29 Sep 2020 18:11:43
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'added' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:56:39
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy 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)	22 Sep 2020 00:50:59
User entered '1'		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error		14 Sep 2020 22:41:34
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:57
User entered empty.		14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:57
User closed query 'PV Query: Please confirm the patient's reported history of convulsive syncope and add to medical history if appropriate, once medical records provided by PCP.' (Site from Safety).		08 Oct 2020 14:04:47
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event, once medical records provided by PCP.' (Site from Safety).		08 Oct 2020 14:04:34
Query 'PV Query: Please confirm the patient's reported history of convulsive syncope and add to medical history if appropriate, once medical records provided by PCP.' answered with 'when discussing the plan with the physician to proceed, which would have included medical record requests and review and a consultation with a neurologist, patient left in the middle of the conversation and refused any more contact by letting calls go unanswered and messages not responded to' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	07 Oct 2020 14:47:41
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event, once medical records provided by PCP.' answered with 'patient refused any more contact, calls were left unreturned, messages were left unanswered, and a certified letter was sent to the patient' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	07 Oct 2020 14:44:46
User opened query 'PV Query: Please confirm the patient's reported history of convulsive syncope and add to medical history if appropriate, once medical records provided by PCP.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 14:21:15
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event, once medical records provided by PCP.' (Site from Safety).		02 Oct 2020 14:20:34

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = Patient was given AMONIA INHALANT and OXYGEN via NASAL CANNULA and Several Vital Signs were obtained. However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 18:11:49
User closed query 'PV Query: Please report if follow-up with the patient was successful. If yes, please provide information regarding any additional exam, diagnostic studies and/or treatment provided.' (Site from Safety).		28 Sep 2020 12:40:43
User closed query 'PV Query: Please confirm the patient's reported history of convulsive syncope and add to medical history if appropriate.' (Site from Safety).		28 Sep 2020 12:40:40
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).		28 Sep 2020 12:40:33
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).		28 Sep 2020 12:40:27
Query 'PV Query: Please report if follow-up with the patient was successful. If yes, please provide information regarding any additional exam, diagnostic studies and/or treatment provided.' answered with 'followups have not yet been successful or there have not been attempts, source does not have records of followups' (Site from Safety).	Elisa Morales (b) (4) (b) (4)	25 Sep 2020 17:52:16
Query 'PV Query: Please confirm the patient's reported history of convulsive syncope and add to medical history if appropriate.' answered with 'waiting on medical records from PCP, the patient did not mention this in initial visits, so we are waiting to review ' (Site from Safety).	Elisa Morales (b) (4) (b) (4)	25 Sep 2020 17:51:02

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'will update medical history if source is updated' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 17:50:30
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'none' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 17:50:01
User opened query 'PV Query: Please report if follow-up with the patient was successful. If yes, please provide information regarding any additional exam, diagnostic studies and/or treatment provided.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 13:11:58
User opened query 'PV Query: Please confirm the patient's reported history of convulsive syncope and add to medical history if appropriate.' (Site from Safety).		24 Sep 2020 13:11:29
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).		24 Sep 2020 13:11:20
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).		24 Sep 2020 13:08:01
Query 'Per DM CLR: SAE Narrative = Patient was given AMONIA INHALANT and OXYGEN via NASAL CANNULA and Several Vital Signs were obtained. However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF.' answered with 'done' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:56:32

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = Patient was given AMONIA INHALANT and OXYGEN via NASAL CANNULA and Several Vital Signs were obtained. However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 00:51:39

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Called to assist with patient with syncopal episode after blood draw. Patient was seen by Dr. (b) (6) for Visit 2 and approved for 2nd IP dose. Patient was responding after sternal rub and use of ammonia inhalant, but then had a generalized seizure lasting 3-5 minutes. Patient was given O2 nasal cannula at 2-4 liters. After patient became more responsive after seizure, she admits to not eating this AM. She only had water. Vitals after seizure: BP 195/89 and pulse 45; pulse ox at 99%. Inquired if patient ever had problems with blood sugars in which she responded "No". Requested glucose finger stick to be drawn, which patient declined. She said it could trigger another syncopal episode. Patient stated that "she was doing fine and would be okay". She said this was convulsive syncope (which happened a long time ago) and nothing else needed to be done". She stated that "she was a cardiologist". Upon arrival of EMS, patient declined transport. I provided witnessed signature to EMS for refusal of transport. Repeat BP 135/78 and pulse 45. CRC (b) (6) spoke with patient regarding her medical history. Patient reported a similar incident about 40 years ago also during a blood draw. Otherwise, since that time there were no further episodes. This medical history was not disclosed during her initial screening. Discussed case with Dr. Veronica Fragoso (PI) and (b) (6) . Recommended in an abundance of caution, that we will hold Visit 2 and report per protocol SAE and advisement from sponsor of how to proceed. Also recommended patient to have Neurology consult and check status of medical records from PCP. Discussed this plan to patient, and she left in the middle of conversation. I told her I will contact her tomorrow once a recommendation was received from the sponsor. Patient was upset and left prior to telling her that a Neurology consult is recommended.'	(b) (4), (b) (6)	14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered 'I'	System	14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered '0'	System	23 Sep 2020 21:50:55
User entered '1'	System	14 Sep 2020 22:39:53

US3322013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:06:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:56:01
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 21:54:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 21:54:41
Data point term sent to Coder	System	23 Sep 2020 21:53:38
User entered 'dizziness'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:56:02
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:56:04
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:56:06
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:56:08
User entered '17 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User closed query 'Per source, start time is 14:00. Please update EDC accordingly per eCRF guidelines ' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:45:30
		02 Nov 2020 21:48:57
Query 'Per source, start time is 14:00. Please update EDC accordingly per eCRF guidelines. ' answered with 'updated' (Site from CRA).	Frances Saubon (b) (4) (b) (4)	20 Oct 2020 19:29:23
User entered '14:00' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	20 Oct 2020 19:29:17
User opened query 'Per source, start time is 14:00. Please update EDC accordingly per eCRF guidelines. ' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 18:06:48
User closed query 'Per CDM re-query: Thank you for your answer. If this Adverse Event was not related with study treatment then please remove Start time. Thank you!' (Site from DM).		09 Oct 2020 09:19:47
User closed query 'Data is required. Please provide.' (Site from System).		09 Oct 2020 09:19:44
Query 'Data is required. Please provide.' answered with 'time removed per CDM query' (Site from System).	Elisa Moralez (b) (4) (b) (4)	08 Oct 2020 13:37:51
Query 'Per CDM re-query: Thank you for your answer. If this Adverse Event was not related with study treatment then please remove Start time. Thank you!' answered with 'a query is automatically issued to enter the time, but per query it has been removed, thank you' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	08 Oct 2020 13:37:40
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 13:37:13
User entered empty; reason for change Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	08 Oct 2020 13:37:13
User opened query 'Per CDM re-query: Thank you for your answer. If this Adverse Event was not related with study treatment then please remove Start time. Thank you!' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 05:59:00

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please clarify if this Adverse Event is related with study treatment or injection or not. Thank you!' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 05:59:00
Query 'Per CDM: Please clarify if this Adverse Event is related with study treatment or injection or not. Thank you!' answered with 'it was not related' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	07 Oct 2020 14:48:15
User opened query 'Per CDM: Please clarify if this Adverse Event is related with study treatment or injection or not. Thank you!' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 07:26:25
Query 'Per CDM: Please clarify if this Adverse Event is related with study treatment or injection or not. Thank you!' canceled (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 07:26:02
User opened query 'Per CDM: Please clarify if this Adverse Event is related with study treatment or injection or not. Thank you!' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 06:52:24
User entered '14:00'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered '17 Aug 2020 14:00'	System	20 Oct 2020 19:29:17
User entered empty.	System	08 Oct 2020 13:37:13
User entered '17 Aug 2020 14:00'	System	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 18:06:52
User entered 'No (N)'	Elisa Moralez (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:06:54
User entered '17 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:06:56
User entered '14:03'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered '17 Aug 2020 14:03'	System	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:06:58
User entered 'Grade 1/Mild (Grade 1/Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:07:00
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:07:03
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:07:05
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:07:22
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	23 Sep 2020 21:53:46
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	23 Sep 2020 21:53:46
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	23 Sep 2020 21:53:29
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:07:24
User entered empty.	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:07:25
User entered empty.	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:07:27
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:46
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:07:28
User entered empty.	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:07:20
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:07:17
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:07:19
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:07:12
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User closed query 'Per CDM: AE started prior to 1st Dose, however 'Relationship to Study Procedure' is 'Related'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:53:48
Query 'Per CDM: AE started prior to 1st Dose, however 'Relationship to Study Procedure' is 'Related'. Please review and update as appropriate. Thank you. ' answered with '1st dose was on 17-Aug-2020 and AE was also on 17-Aug-2020. AE occurred during the visit when blood was being collected.' (Site from DM).	Frances Saubon (b) (4) (b) (4)	18 Nov 2020 15:31:14
User opened query 'Per CDM: AE started prior to 1st Dose, however 'Relationship to Study Procedure' is 'Related'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 07:37:09
DataPoint Verified.		20 Oct 2020 18:07:11
User entered 'Related (RELATED)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:07:09
User entered 'None (NONE)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:07:14
User entered 'I'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 18:07:31
User entered '0'	Elisa Moralez (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 18:07:33
User entered '0'	Elisa Moralez (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:07:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:07:36
User entered empty.	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:07:37
User entered empty.	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered '0'	System	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered 'I'	System	23 Sep 2020 21:53:29

US3322013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:06:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered '0'	System	23 Sep 2020 21:53:29

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:06:51

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint Verified.	Heather Davis (b) (4)	08 Apr 2021 17:01:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	23 Sep 2020 21:48:51

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:51

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 06:24:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 06:24:46
Data point term sent to Coder	System	23 Sep 2020 21:50:35
User entered 'Mutivitamins'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:49:57

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'No (N)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 13:33:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 22:01:42
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:49:57

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'general health'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:49:57

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'l'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:49:57

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'tablet (TABLET)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:49:57

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered empty.	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:49:57

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'once daily (QD)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:49:57

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered empty.	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:49:57

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:49:57

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered empty.	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:49:57

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'un UNK 2010'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:49:57

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:49:57

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:49:57

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered empty.	Elisa Moralez (b) (4)	23 Sep 2020 21:49:57

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 21:49:57

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered '1'	System	23 Sep 2020 21:49:57

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered '1'	System	23 Sep 2020 21:49:57

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:06:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered '804 (804)'	System	23 Sep 2020 21:49:57

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 09:33:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 09:33:43
Data point term sent to Coder	System	25 Sep 2020 13:34:33
User entered 'Oxygen'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 13:33:53

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 13:33:53

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'convulsive syncope'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 13:33:53

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint Verified.	(b) (4), (b) (6)	14 Mar 2021 17:46:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User closed query 'Per CDM: Please review dose because only numericals are allowed on dose field. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 20:50:58
Query 'Per CDM: Please review dose because only numericals are allowed on dose field. Thank you!' answered with 'Updated, Thank You!' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 21:22:29
DataPoint Un-verified.	(b) (4), (b) (6)	17 Dec 2020 21:22:20
User entered '3' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 21:22:20
User opened query 'Per CDM: Please review dose because only numericals are allowed on dose field. Thank you!' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 09:52:43
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered '2-4'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 13:33:53

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'Other (OTHER)'	Elisa Moralez (b) (4)	25 Sep 2020 13:33:53

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'liters'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 13:33:53

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'once (ONCE)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 13:33:53

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 13:33:53

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 13:33:53

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 13:33:53

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered '14 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 13:33:53

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered '0'	Elisa Moralez (b) (4)	25 Sep 2020 13:33:53

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 13:33:53

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered '14 Sep 2020'	Elisa Moralez (b) (4)	25 Sep 2020 13:33:53

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 13:33:53

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered empty.	System	25 Sep 2020 13:33:53

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered empty.	System	25 Sep 2020 13:33:53

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:06:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered empty.	System	25 Sep 2020 13:33:53

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:51

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: OTHER PSYCHOSTIMULANTS AND NOOTROPICS, PRODUCT: AMMONIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:20:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:20:03
Data point term sent to Coder	System	07 Oct 2020 13:25:43
User entered 'ammonia inhalant'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 13:25:12

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 13:25:12

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'convulsive syncope'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 13:25:12

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint Verified.		16 Mar 2021 15:34:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User closed query 'Per CDM: Please review and update dose because at the moment dose is entered as ".33". Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 20:51:03
Query 'Per CDM: Please review and update dose because at the moment dose is entered as ".33". Thank you!' answered with 'Updated, Thank You!' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 21:21:55
DataPoint Un-verified.		17 Dec 2020 21:21:45
User entered '.3' reason for change: Data Entry Error		17 Dec 2020 21:21:45
User opened query 'Per CDM: Please review and update dose because at the moment dose is entered as ".33". Thank you!' (Site from DM).		17 Dec 2020 09:52:18
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered '.33'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 13:25:12

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'Other (OTHER)'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 13:25:12

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'cubic centimeter'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 13:25:12

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'once (ONCE)'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 13:25:12

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered empty.	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 13:25:12

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 13:25:12

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered empty.	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 13:25:12

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered '14 Sep 2020'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 13:25:12

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered '0'	Frances Saubon (b) (4)	07 Oct 2020 13:25:12

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 13:25:12

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered '14 Sep 2020'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 13:25:12

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:50:12
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 13:25:12

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered empty.	System	07 Oct 2020 13:25:12

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered empty.	System	07 Oct 2020 13:25:12

US3322013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:06:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User entered empty.	System	07 Oct 2020 13:25:12

US3322013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:06:51

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'No (N)' reason for change: Data Entry Error	Frances Saubon (b) (4)	07 Oct 2020 13:32:58
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	23 Sep 2020 21:54:23

US3322013

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:06:51

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:59:39
User closed query 'Per CDM-If participant was lost to follow-up after receiving dose, use date of last contact. Kindly review and consider to update last date of contact else clarify. Thank you.' (Site from DM).		17 Dec 2020 14:32:26
Query 'Per CDM-If participant was lost to follow-up after receiving dose, use date of last contact. Kindly review and consider to update last date of contact else clarify. Thank you.' answered with 'date has been changed to last point of confirmed contact, please note that the patient was not officially discontinued until Dec 7' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	16 Dec 2020 22:04:22
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	16 Dec 2020 22:03:48
User entered '14 Sep 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	16 Dec 2020 22:03:48
User opened query 'Per CDM-If participant was lost to follow-up after receiving dose, use date of last contact. Kindly review and consider to update last date of contact else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 04:29:45
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:04:36
User entered '07 Dec 2020'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 23:08:41

US3322013

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:06:51

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:04:36
User entered 'Lost To Follow-up (LOST TO FOLLOW-UP)'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 23:08:41

US3322013

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:06:51

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 12:10:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:04:36
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 23:08:41

US3322013

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:06:51

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 01:09:30
User closed query ' Per CDM-If participant was lost to follow-up after receiving dose, use date of last contact.Kindly review and consider to update last date of contact else clarify.Thank you. ' (Site from DM).		17 Dec 2020 14:32:34
Query ' Per CDM-If participant was lost to follow-up after receiving dose, use date of last contact.Kindly review and consider to update last date of contact else clarify.Thank you. ' answered with 'changed per request' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	16 Dec 2020 22:05:18
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	16 Dec 2020 22:05:11
User entered '14 Sep 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	16 Dec 2020 22:05:11
User opened query ' Per CDM-If participant was lost to follow-up after receiving dose, use date of last contact.Kindly review and consider to update last date of contact else clarify.Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 04:30:33
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:04:44
User entered '07 Dec 2020'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 23:09:03

US3322013

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:06:51

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:04:44
User entered 'Lost To Follow-up (LOST TO FOLLOW-UP)'	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 23:09:03

US3322013

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:06:51

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 12:10:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:04:44
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 23:09:03

US3322013

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:06:51

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:04:44
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 23:09:03

US3322013

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:06:51

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:04:44
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 23:09:03

US3322013

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:06:51

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:04:44
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 23:09:03

US3322013

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:06:51

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:04:44
User entered empty.	Frances Saubon (b) (4) (b) (4)	11 Dec 2020 23:09:03

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'USA-US060-2020-MRNA-1273-P301000001'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Yes (Y)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Yes (Y)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Veronica'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Fragoso'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered '6550 Mapleridge Street'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Houston'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'TX'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered '77081'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint Verified.		14 Mar 2021 17:45:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:41:01
Un-reviewed for Safety.	System	24 Sep 2020 02:01:14
DataPoint Un-verified.	System	24 Sep 2020 02:01:14
User entered 'US'	System	24 Sep 2020 02:01:14
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:00:57
DataPoint Verified.		23 Sep 2020 15:58:23
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 13:23:58
User entered 'US' (non-conformant).	System	15 Sep 2020 18:37:36

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '4'	System	08 Oct 2020 14:05:09
User entered '3'	System	28 Sep 2020 12:41:13
User entered '2'	System	24 Sep 2020 02:01:14
User entered '1'	System	15 Sep 2020 18:37:36

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'USA-US060-2020-MRNA-1273-P301000001'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Yes (Y)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Yes (Y)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Veronica'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Fragoso'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered '6550 Mapleridge Street'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Houston'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'TX'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered '77081'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint Verified.		14 Mar 2021 17:45:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:41:01
Un-reviewed for Safety.	System	24 Sep 2020 02:01:14
DataPoint Un-verified.	System	24 Sep 2020 02:01:14
User entered 'US'	System	24 Sep 2020 02:01:14
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:00:57
DataPoint Verified.		23 Sep 2020 15:58:23
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 13:23:58
User entered 'US' (non-conformant).	System	15 Sep 2020 18:37:36

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '4'	System	08 Oct 2020 14:05:09
User entered '3'	System	28 Sep 2020 12:41:13
User entered '2'	System	24 Sep 2020 02:01:14
User entered '1'	System	15 Sep 2020 18:37:36

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:06:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
User entered '15/Sep/2020 14:37'	System	15 Sep 2020 18:37:36

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:06:51

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)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 02:00:57
DataPoint Verified.		23 Sep 2020 15:58:23
User entered 'I'		15 Sep 2020 18:37:36

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'USA-US060-2020-MRNA-1273-P301000001'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Yes (Y)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Yes (Y)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Veronica'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Fragoso'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered '6550 Mapleridge Street'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Houston'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'TX'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered '77081'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint Verified.		14 Mar 2021 17:45:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:41:01
Un-reviewed for Safety.	System	24 Sep 2020 02:01:14
DataPoint Un-verified.	System	24 Sep 2020 02:01:14
User entered 'US'	System	24 Sep 2020 02:01:14
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:00:57
DataPoint Verified.		23 Sep 2020 15:58:23
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 13:23:58
User entered 'US' (non-conformant).	System	15 Sep 2020 18:37:36

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '4'	System	08 Oct 2020 14:05:09
User entered '3'	System	28 Sep 2020 12:41:13
User entered '2'	System	24 Sep 2020 02:01:14
User entered '1'	System	15 Sep 2020 18:37:36

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:06:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint Verified.		14 Mar 2021 17:45:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '23/Sep/2020 22:01'	(b) (4) System	24 Sep 2020 02:01:14

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:06:51

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)	28 Apr 2021 15:17:11
DataPoint Verified.		14 Mar 2021 17:45:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:41:01
User entered 'I'		24 Sep 2020 02:01:14

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'USA-US060-2020-MRNA-1273-P301000001'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Yes (Y)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Yes (Y)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Veronica'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Fragoso'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered '6550 Mapleridge Street'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Houston'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'TX'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered '77081'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint Verified.		14 Mar 2021 17:45:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:41:01
Un-reviewed for Safety.	System	24 Sep 2020 02:01:14
DataPoint Un-verified.	System	24 Sep 2020 02:01:14
User entered 'US'	System	24 Sep 2020 02:01:14
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:00:57
DataPoint Verified.		23 Sep 2020 15:58:23
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 13:23:58
User entered 'US' (non-conformant).	System	15 Sep 2020 18:37:36

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '4'	System	08 Oct 2020 14:05:09
User entered '3'	System	28 Sep 2020 12:41:13
User entered '2'	System	24 Sep 2020 02:01:14
User entered '1'	System	15 Sep 2020 18:37:36

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:06:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint Verified.		14 Mar 2021 17:45:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '28/Sep/2020 12:41'	(b) (4) System	28 Sep 2020 12:41:13

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:06:51

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)	28 Apr 2021 15:17:11
DataPoint Verified.		14 Mar 2021 17:45:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:04:58
User entered 'I'		28 Sep 2020 12:41:13

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'USA-US060-2020-MRNA-1273-P301000001'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Yes (Y)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'No (N)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Yes (Y)'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Veronica'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Fragoso'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered '6550 Mapleridge Street'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'Houston'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered 'TX'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:58:23
Reviewed for Safety.		15 Sep 2020 18:37:29
User entered '77081'	System	15 Sep 2020 18:36:54

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint Verified.		14 Mar 2021 17:45:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:41:01
Un-reviewed for Safety.	System	24 Sep 2020 02:01:14
DataPoint Un-verified.	System	24 Sep 2020 02:01:14
User entered 'US'	System	24 Sep 2020 02:01:14
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 02:00:57
DataPoint Verified.		23 Sep 2020 15:58:23
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 13:23:58
User entered 'US' (non-conformant).	System	15 Sep 2020 18:37:36

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:06:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '4'	System	08 Oct 2020 14:05:09
User entered '3'	System	28 Sep 2020 12:41:13
User entered '2'	System	24 Sep 2020 02:01:14
User entered '1'	System	15 Sep 2020 18:37:36

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:06:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:17:11
DataPoint Verified.		14 Mar 2021 17:45:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered '08/Oct/2020 14:05'	(b) (4) System	08 Oct 2020 14:05:09

US3322013

Folder: SAE USA-US060-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:06:51

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)	28 Apr 2021 15:17:11
DataPoint Verified.		14 Mar 2021 17:45:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:36
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:05:09