

US3302310 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:22:52

All time stamps listed in this document are displayed in GMT

**US3302310**

**Form: Participant Creation**

**Data signed:** (b) (4) 19 Feb 2021 19:11:13

**Generated On:** 11 Aug 2021 22:22:52

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[Participant ID](#)

US3302310

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

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US3302310

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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) 19 Feb 2021 19:11:18

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Date of Birth (MMM yyyy)	(b) (6) 1987
Age	33
Age Units	YEARS
Age (Derived)	33
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" 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) 19 Feb 2021 19:11:18

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	20 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) 19 Feb 2021 19:11:18

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 19:11:18

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Were any significant conditions reported?

Yes ☐

No ☒

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:11:18

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	16:07 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 16:07
Height (xxx.x)	69 in
Weight (xxx.x)	125 lb
BMI (xxx.x)	18.49787 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:11:18

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 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) 19 Feb 2021 19:11:18

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Date of assessment (dd MMM yyyy) 20 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) \_\_\_\_\_  
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 19:11:18

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Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	20 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 19:11:18

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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 ☒

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**Specify**

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**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 19:11:18

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 106324

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) 19 Feb 2021 19:11:18**

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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) 19 Feb 2021 19:11:18

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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)	20 AUG 2020
Time of assessment (00:00-23:59)	16:07 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 16:07
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

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)	20 AUG 2020
Time of assessment (00:00-23:59)	16:57 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 16:57
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:11:18

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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: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 19:11:18

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Was the pregnancy test performed? Yes ☐  
No ☒

Date of test (dd MMM yyyy) \_\_\_\_\_

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:11:18

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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) 20 AUG 2020

What was the treatment time? (00:00-23:59) 16:27 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 16:27

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) 19 Feb 2021 19:11:18

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Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 AUG 2020

Collection time (00:00-23:59)

16:13 (24 HR)

Collection date and time (derived)

20 AUG 2020 16:13

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Collection date (dd MMM yyyy)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:10	20 AUG 2020 16:10
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

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: 11 Aug 2021 22:22:52

**TIMEPOINT**

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

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

20 AUG 2020 16:48

PC Open Date & Time

20 AUG 2020 16:47

PC Close Date & Time

20 AUG 2020 19:17

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

**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 97.5 °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	20 AUG 2020 20:17
PC Open Date & Time	20 AUG 2020 20:12
PC Close Date & Time	21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:52

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**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

97.3 °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 16:53

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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 17:38

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	23 AUG 2020 16:01
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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):

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

24 AUG 2020 18:08

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

25 AUG 2020 18:18

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

26 AUG 2020 19:47

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 16:48

PC Open Date & Time

20 AUG 2020 16:47

PC Close Date & Time

20 AUG 2020 19:17

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

**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

20 AUG 2020 20:18

PC Open Date & Time

20 AUG 2020 20:12

PC Close Date & Time

21 AUG 2020 11:59

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:52

**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

21 AUG 2020 16:51

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:52

**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

22 AUG 2020 17:38

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:52

**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

23 AUG 2020 16:01

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:52

**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

24 AUG 2020 18:08

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:52

**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

25 AUG 2020 18:18

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:52

**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

26 AUG 2020 19:47

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 16:49
PC Open Date & Time	20 AUG 2020 16:47
PC Close Date & Time	20 AUG 2020 19:17

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 20:18
PC Open Date & Time	20 AUG 2020 20:12
PC Close Date & Time	21 AUG 2020 11:59

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:52

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 16:52
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

46 of 2525

EAB) (1725)

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 17:39
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

48 of 2525

EAB) (1725)

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:52

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 16:01
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 2525

EAB) (1725)

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:52

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 18:09
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:52

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 18:19
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

		Yes <input type="checkbox"/>
PC Time stamp	26 AUG 2020 19:48	
PC Open Date & Time	26 AUG 2020 12:00	
PC Close Date & Time	27 AUG 2020 11:59	

US3302310

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302310

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302310

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302310

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302310

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

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*

US3302310

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302310

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:22:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:22:52

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)	16 SEP 2020
Time of assessment (00:00-23:59)	07:54 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 07:54
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)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:22:52

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	08:43 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 08:43
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3302310

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:22:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3302310

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:22:52

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	16 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3302310

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:22:52

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) 16 SEP 2020

What was the treatment time? (00:00-23:59) 08:13 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 08:13

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

US3302310

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:22:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 SEP 2020

Collection time (00:00-23:59)

08:00 (24 HR)

Collection date and time (derived)

16 SEP 2020 08:00

US3302310

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:22:52

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:58	16 SEP 2020 07:58
Nasopharyngeal Swab 2	Yes	07:58	16 SEP 2020 07:58

US3302310

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:22:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

**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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 08:33

PC Open Date & Time

16 SEP 2020 08:33

PC Close Date & Time

16 SEP 2020 11:03

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

**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 97.2 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes ☐ No ☒

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

PC Time Stamp	16 SEP 2020 17:51
PC Open Date & Time	16 SEP 2020 11:58
PC Close Date & Time	17 SEP 2020 11:59

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:52

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**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

97.2 °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 SEP 2020 17:13

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 07:58

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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 SEP 2020 16:07

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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 SEP 2020 16:51

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

21 SEP 2020 19:27

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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 SEP 2020 19:12

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 08:33

PC Open Date & Time

16 SEP 2020 08:33

PC Close Date & Time

16 SEP 2020 11:03

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

**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

16 SEP 2020 17:51

PC Open Date & Time

16 SEP 2020 11:58

PC Close Date & Time

17 SEP 2020 11:59

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:52

**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

17 SEP 2020 17:12

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:52

**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 SEP 2020 07:58

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:52

**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

19 SEP 2020 16:07

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:52

**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

20 SEP 2020 16:51

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:52

**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

21 SEP 2020 19:27

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:52

**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

22 SEP 2020 19:12

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 08:34
PC Open Date & Time	16 SEP 2020 08:33
PC Close Date & Time	16 SEP 2020 11:03

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 17:51
PC Open Date & Time	16 SEP 2020 11:58
PC Close Date & Time	17 SEP 2020 11:59

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:52

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 17:12
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:52

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 07:59
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 16:08
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:52

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 16:51
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:52

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 19:27
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:52

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 19:13
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3302310

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302310

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302310

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302310

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302310

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302310

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302310

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:22:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3302310

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:22:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	07:41 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 07:41
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3302310

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:22:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 2020

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

US3302310

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:22:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 OCT 2020

Collection time (00:00-23:59)

07:45 (24 HR)

Collection date and time (derived)

14 OCT 2020 07:45

US3302310

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:11:19

Generated On: 11 Aug 2021 22:22:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

<b>TIMEPOINT</b>	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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 OCT 2020 06:05:08
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

US3302310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

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 checked="" 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 checked="" 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 checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 OCT 2020 13:54:46
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3302310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

03 NOV 2020 07:23:18

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3302310

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

17 NOV 2020 06:15:42

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 15:16:59
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 103

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

28 NOV 2020 08:00:23

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 110

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

05 DEC 2020 07:23:40

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 07:45:31
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 124
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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 07:59:41
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 131

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

26 DEC 2020 08:42:24

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 138

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

02 JAN 2021 09:17:50

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 145

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

09 JAN 2021 08:53:15

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 152

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

16 JAN 2021 04:58:56

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 159

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

25 JAN 2021 09:57:53

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 166

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

30 JAN 2021 07:39:52

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 173

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

06 FEB 2021 08:16:52

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 180
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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 08:17:30
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 187

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

20 FEB 2021 07:16:53

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 194
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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 FEB 2021 11:03:13
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 201
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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 07:29:03
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 208
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 checked="" 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 checked="" type="radio"/> Yes <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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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 checked="" type="radio"/>
Date and time of submission	13 MAR 2021 05:58:28
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 215

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

20 MAR 2021 07:52:44

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 222

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

27 MAR 2021 08:29:16

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 229

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

03 APR 2021 08:00:05

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

<b>TIMEPOINT</b>	DAY 236
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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 APR 2021 08:53:25
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 243

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

17 APR 2021 07:35:05

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 250

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

24 APR 2021 08:52:58

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 257

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

01 MAY 2021 08:08:19

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 264
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 271
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 278
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 285
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 292
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

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US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 299
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

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US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 306
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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19 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2021 23:59

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US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 313

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please 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 ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 320
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 327
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 334
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 341
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 348
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 355
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 362
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 369
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 376
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 383
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 390
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 397

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please 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 ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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18 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2021 23:59

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US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 404
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 411
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 418
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 425
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 432
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 439
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 446
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

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US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 453
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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13 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 NOV 2021 23:59

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US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 460
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 467
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 474
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 481

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please 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 ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 488
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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18 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 DEC 2021 23:59

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US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 495
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 502
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 509
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 516
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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15 JAN 2022 00:01

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19 JAN 2022 23:59

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US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 523
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 530
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT

DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please 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 ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 544
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 551
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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19 FEB 2022 00:01

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23 FEB 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT

DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please 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 ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

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02 MAR 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please 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 ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

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09 MAR 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please 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 ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

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16 MAR 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 579

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please 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 ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 586
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please 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 ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 600
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"/>

**US3302310**

**Folder: New 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.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 607
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

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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.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 614
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 621
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 628
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 635
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 642
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 649
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 656
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 663
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUN 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 670
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☐  
Yes ☐

Please 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 ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) \_\_\_\_\_

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐  
Yes ☐

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

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29 JUN 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 684
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 691
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 698
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 705
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"/>

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**Folder: New 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.

I confirm I have read this message and will call the study clinic immediately ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 712
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"/>

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 719
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New 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.

I confirm I have read this message and will call the study clinic immediately ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 726
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 733
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 740
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

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**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 747
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 754
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"/>

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**Folder: New 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.

I confirm I have read this message and will call the study clinic immediately ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 761
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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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="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"/>

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**Folder: New 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.

I confirm I have read this message and will call the study clinic immediately ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 768
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"/>

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please 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 ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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 ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 782
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

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US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 789
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3302310

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:52

TIMEPOINT	DAY 796
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"/>

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

**US3302310**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 11 Aug 2021 22:22:52**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		06 MAR 2021 07:29:17

US3302310

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302310

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302310

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302310

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302310

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302310

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302310

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302310

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302310

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 18:19:51

Generated On: 11 Aug 2021 22:22:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	23 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3302310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 16:00:44

Generated On: 11 Aug 2021 22:22:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 MAR 2021
Time of assessment (00:00-23:59)	15:54 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 15:54
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3302310

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 18:19:51

Generated On: 11 Aug 2021 22:22:52

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3302310

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 18:19:51

Generated On: 11 Aug 2021 22:22:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 MAR 2021

Collection time (00:00-23:59)

15:56 (24 HR)

Collection date and time (derived)

23 MAR 2021 15:56

US3302310

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:19:51

Generated On: 11 Aug 2021 22:22:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302310

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 12:33:42

Generated On: 11 Aug 2021 22:22:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302310

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 12:33:42

Generated On: 11 Aug 2021 22:22:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3302310**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3302310**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3302310

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Date of Contact	23 NOV 2020
Time of Contact	16:10
Date and Time of Contact (derived)	23 NOV 2020 16:10
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

US3302310

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Feb 2021 19:11:16

Generated On: 11 Aug 2021 22:22:52

Date of Visit	23 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	23 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3302310

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Respiratory Rate \_\_\_\_\_

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Oxygen Saturation \_\_\_\_\_

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date \_\_\_\_\_

US3302310

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

If Yes to either Did subject require any of the following:

**Ventilator Support:**

High-Flow Oxygen? Yes ☐ No ☒

Start Date

End Date

Non-Invasive Ventilation? Yes ☐ No ☒

Start Date

End Date

Mechanical Ventilation? Yes ☐ No ☒

Start Date

End Date

ECMO? Yes ☐ No ☒

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐ No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐ No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐ No ☒

Start Date

US3302310

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Hepatic Dysfunction? Yes ☐  
No ☒

Start Date

Neurologic Dysfunction? Yes ☐  
No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐  
No ☒

Date of Assessment

Radiographical Evidence Yes ☐  
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐  
No ☒

Start Date

End Date

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Date of Contact	26 OCT 2020
Time of Contact	09:15
Date and Time of Contact (derived)	26 OCT 2020 09:15
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

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Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (7)

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 19:11:17

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Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	01 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3302310

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Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	02 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	03 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	05 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Feb 2021 19:11:16

Generated On: 11 Aug 2021 22:22:52

Date of Visit	26 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	26 OCT 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	LUXOR SCIENTIFIC
CLIA Certified?	Yes <input checked="" type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Respiratory Rate \_\_\_\_\_

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☐ No ☐

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Oxygen Saturation \_\_\_\_\_

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date \_\_\_\_\_

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

If Yes to either Did subject require any of the following:

**Ventilator Support:**

High-Flow Oxygen? Yes ☐  
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐  
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐  
No ☐

Start Date

End Date

ECMO? Yes ☐  
No ☐

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐  
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐  
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐  
No ☒

Start Date

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Hepatic Dysfunction? Yes ☐  
No ☒

Start Date

Neurologic Dysfunction? Yes ☐  
No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐  
No ☒

Date of Assessment

Radiographical Evidence Yes ☐  
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐  
No ☒

Start Date

End Date

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

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[Generate Next COVID-19 Assessment](#)

Yes ☒  
No ☐

---

**US3302310**

**Folder: Illness Visit (1)**

**Form: Saliva Collection**

**Data signed:** (b) (4) 19 Feb 2021 19:11:17

**Generated On: 11 Aug 2021 22:22:52**

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	28 OCT 2020
Day 5	Yes	30 OCT 2020
Day 7	Yes	1 NOV 2020
Day 9	Yes	3 NOV 2020
Day 14	Yes	08 NOV 2020
Day 21	Yes	15 NOV 2020
Day 28	Yes	23 NOV 2020

US3302310

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3302310

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 09:30
Height (xxx.x)	69 in
Weight (xxx.x)	130 lb
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3302310

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3302310

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

26 OCT 2020

US3302310

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:11:16

Generated On: 11 Aug 2021 22:22:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3302310

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:11:16

Generated On: 11 Aug 2021 22:22:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 NOV 2020
Time of assessment (00:00-23:59)	16:15 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 16:15
Height (xxx.x)	69 in
Weight (xxx.x)	124 lb
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3302310

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:11:16

Generated On: 11 Aug 2021 22:22:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 NOV 2020

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

US3302310

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 05 Mar 2021 21:43:07

Generated On: 11 Aug 2021 22:22:52

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 NOV 2020

US3302310

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	26 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3302310

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

Form: Unblinding

Data signed: (b) (4) 29 Apr 2021 12:33:42

Generated On: 11 Aug 2021 22:22:52

Date of updated informed consent ( <i>dd MMM yyyy</i> )	26 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	26 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

**US3302310**

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

**Form: Vital Signs - Dosing**

**Data signed:** (b) (4) 19 Feb 2021 19:11:18

**Generated On: 11 Aug 2021 22:22:52**

Height	
Weight	
BMI (xxx.x)	

US3302310

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Height	
Weight	
BMI (xxx.x)	
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)	26 JAN 2021
Time of assessment (00:00-23:59)	15:36 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 15:36
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3302310

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Height	
Weight	
BMI (xxx.x)	
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)	26 JAN 2021
Time of assessment (00:00-23:59)	16:12 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 16:12
Temperature (xxx.x)	99.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3302310

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

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 18:19:51

Generated On: 11 Aug 2021 22:22:52

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3302310

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

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 26 JAN 2021

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

US3302310

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 JAN 2021

What was the treatment time? (00:00-23:59) 15:40 (24 HR)

Treatment Date and Time (derived) 26 JAN 2021 15:40

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

US3302310

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 JAN 2021

Collection time (00:00-23:59)

15:17 (24 HR)

Collection date and time (derived)

26 JAN 2021 15:17

US3302310

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	26 JAN 2021
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Collection time (00:00 - 23:59)	15:15
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Collection Date and Time (derived)	26 JAN 2021 15:15
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US3302310

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:11:17

Generated On: 11 Aug 2021 22:22:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302310

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302310

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3302310

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 03 Mar 2021 18:56:35

Generated On: 11 Aug 2021 22:22:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3302310

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Mar 2021 18:56:35

Generated On: 11 Aug 2021 22:22:52

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)	24 FEB 2021
Time of assessment (00:00-23:59)	15:58 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 15:58
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)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3302310

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Mar 2021 18:56:35

Generated On: 11 Aug 2021 22:22:52

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)	24 FEB 2021
Time of assessment (00:00-23:59)	16:33 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 16:33
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3302310

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Mar 2021 18:56:35

Generated On: 11 Aug 2021 22:22:52

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3302310

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 03 Mar 2021 18:56:35

Generated On: 11 Aug 2021 22:22:52

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	24 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3302310

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 03 Mar 2021 18:56:35

Generated On: 11 Aug 2021 22:22:52

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 24 FEB 2021

What was the treatment time? (00:00-23:59) 16:02 (24 HR)

Treatment Date and Time (derived) 24 FEB 2021 16:02

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

US3302310

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 18:56:35

Generated On: 11 Aug 2021 22:22:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302310

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 18:56:35

Generated On: 11 Aug 2021 22:22:52

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302310

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 18:56:35

Generated On: 11 Aug 2021 22:22:52

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302310

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 18:19:51

Generated On: 11 Aug 2021 22:22:52

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3302310

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Mar 2021 18:19:51

Generated On: 11 Aug 2021 22:22:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	23 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	15:54 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 15:54
Temperature ( <i>xxx.x</i> )	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	69 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3302310

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 18:19:51

Generated On: 11 Aug 2021 22:22:52

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3302310

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 18:19:51

Generated On: 11 Aug 2021 22:22:52

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 MAR 2021

Collection time (00:00-23:59)

15:56 (24 HR)

Collection date and time (derived)

23 MAR 2021 15:56

US3302310

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 19:11:13

Generated On: 11 Aug 2021 22:22:52

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Did the participant experience any adverse events?

Yes ☒

No ☐

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If Yes, enter details on the Adverse Events form.

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US3302310

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Feb 2021 19:11:13

Generated On: 11 Aug 2021 22:22:52

AEID	USA-US087-2020-MRNA-1273-P30 1000004
Adverse event	COVID-19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	26 OCT 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)	05 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" 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"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Feb 2021 19:11:13

Generated On: 11 Aug 2021 22:22:52

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3302310

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Feb 2021 19:11:13

Generated On: 11 Aug 2021 22:22:52

AEID	
Adverse event	COVID-19
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)	23 NOV 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)	23 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
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	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Feb 2021 19:11:13

Generated On: 11 Aug 2021 22:22:52

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 19:11:14

Generated On: 11 Aug 2021 22:22:52

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

Yes ☒

No ☐

---

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

---

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 19:11:13

Generated On: 11 Aug 2021 22:22:52

Name of Medication MICRONOR

Prophylaxis Yes ☒  
No ☐

Indication ORAL CONTRACEPTIVE

Dose per administration 0.35

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)

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 19:11:13

Generated On: 11 Aug 2021 22:22:52

	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 MAR 2019	
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"/>

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 19:11:13

Generated On: 11 Aug 2021 22:22:52

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication VACCINE

Dose per administration 1

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

If dose unit is Other, specify INJECTION

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 19:11:13

Generated On: 11 Aug 2021 22:22:52

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input 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)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 OCT 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"/>

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 19:11:13

Generated On: 11 Aug 2021 22:22:52

Name of Medication ADVIL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE (COVID SYMPTOM)

Dose per administration 200

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)

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 19:11:13

Generated On: 11 Aug 2021 22:22:52

	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)		01 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3302310

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 19:11:16

Generated On: 11 Aug 2021 22:22:52

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3302310

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:22:52

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

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3302310

Folder: SAE USA-US087-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

SAEID	USA-US087-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3302310

Folder: SAE USA-US087-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

SAEID	USA-US087-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	09/NOV/2020 20:14
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

US3302310

Folder: SAE USA-US087-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 19:11:18

Generated On: 11 Aug 2021 22:22:52

SAEID	USA-US087-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	FELDMAN
Site Address: Street	141 HAROLD FLEMING COURT
Site Address: City	SPARTANBURG
Site Address: State	
Site Address: Postal Code	29303
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	17/NOV/2020 00:00
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

US3302310 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

**US3302310**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:22:52**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
User entered 'US3302310'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 20:04:48

**US3302310**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	20 Aug 2020 20:19:27

**US3302310**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 20:04:49

US3302310

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Clinic (Clinic)'	(b) (4) Brittany Belcher (b) (4)	20 Aug 2020 20:19:27

**US3302310**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User entered 'SCRN'	System	20 Aug 2020 20:19:27

**US3302310**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:22:52**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:27
User entered (b) (6) 1987'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 20:04:50

**US3302310**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:22:52**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:27
User entered '33'	Brittany Belcher (b) (4)	20 Aug 2020 20:19:21

**US3302310**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:22:52**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User entered 'YEARS'	System	20 Aug 2020 20:19:21

**US3302310**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:22:52**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User entered '33'	System	20 Aug 2020 20:19:36

**US3302310**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:22:52**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:27
User entered 'Female (F)'	Brittany Belcher (b) (4)	20 Aug 2020 20:19:21

US3302310

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:22:52

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:27
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Brittany Belcher (b) (4)	20 Aug 2020 20:19:21

**US3302310**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:22:52**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:27
User entered 'l'	Brittany Belcher (b) (4)	20 Aug 2020 20:19:21

**US3302310**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:22:52**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:27
User entered '0'	Brittany Belcher (b) (4)	20 Aug 2020 20:19:21

**US3302310**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:22:52**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:27
User entered '0'	Brittany Belcher (b) (4)	20 Aug 2020 20:19:21

**US3302310**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:22:52**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:27
User entered '0'	Brittany Belcher (b) (4)	20 Aug 2020 20:19:21

**US3302310**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:22:52**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:27
User entered '0'	Brittany Belcher (b) (4)	20 Aug 2020 20:19:21

**US3302310**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:22:52**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:27
User entered '0'	Brittany Belcher (b) (4)	20 Aug 2020 20:19:21

**US3302310**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:22:52**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:27
User entered empty.	Brittany Belcher (b) (4)	20 Aug 2020 20:19:21

**US3302310**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:22:52**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:27
User entered '0'	Brittany Belcher (b) (4)	20 Aug 2020 20:19:21

**US3302310**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:22:52**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:03:27
User entered '0'	Brittany Belcher (b) (4)	20 Aug 2020 20:19:21

**US3302310**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:22:52**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:06
User entered '20 Aug 2020'	Brittany Belcher (b) (4)	20 Aug 2020 20:19:36

**US3302310**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User entered 'Aug 2020'	System	20 Aug 2020 20:19:36

**US3302310**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User entered '2020'	System	20 Aug 2020 20:19:36

US3302310

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:22:52

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:06
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	23 Oct 2020 14:35:44
User entered 'Amendment 1 (1)'	Brittany Belcher (b) (4)	20 Aug 2020 20:19:36

**US3302310**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:06
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	20 Aug 2020 20:19:36

**US3302310**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:22:52**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:06
User entered empty.	Brittany Belcher (b) (4)	20 Aug 2020 20:19:36

**US3302310**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:22:52**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:06
User entered empty.	Brittany Belcher (b) (4)	20 Aug 2020 20:19:36

**US3302310**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:22:52**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:06
User entered 'No (N)'	Brittany Belcher (b) (4)	20 Aug 2020 20:19:36

**US3302310**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:22:52**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:06
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 20:04:49

**US3302310**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:22:52**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User entered 'I'	System	20 Aug 2020 20:19:40

**US3302310**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:33
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	20 Aug 2020 20:19:40

**US3302310**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 11 Aug 2021 22:22:52**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	20 Aug 2020 20:19:48

**US3302310**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:51
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	20 Aug 2020 20:20:25

US3302310

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:51
User entered '20 Aug 2020'	Brittany Belcher (b) (4)	20 Aug 2020 20:20:25

**US3302310**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:51
User entered '16:07'	Brittany Belcher (b) (4)	20 Aug 2020 20:20:25

**US3302310**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User entered '20 Aug 2020 16:07'	System	20 Aug 2020 20:20:25

**US3302310**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:51
User entered '69' in	Brittany Belcher (b) (4)	20 Aug 2020 20:20:25
DataPoint set to visible.	System	20 Aug 2020 20:19:40

US3302310

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:52

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:51
User entered '125' lb	Brittany Belcher (b) (4)	20 Aug 2020 20:20:25
DataPoint set to visible.	System	20 Aug 2020 20:19:40

**US3302310**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
Amendment Manager: User entered '18.49787'	System	17 Sep 2020 00:17:04
User entered '18.5'	System	20 Aug 2020 20:20:25
DataPoint set to visible.	System	20 Aug 2020 20:19:40

**US3302310**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User entered 'kg/m2'	System	20 Aug 2020 20:20:25
DataPoint set to visible.	System	20 Aug 2020 20:19:40

US3302310

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:51
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 06:06:10
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'done' (Site from DM).	Brittany Belcher (b) (4)	07 Oct 2020 13:35:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:35:18
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 08:36:41
User entered '98.7' F	Brittany Belcher (b) (4)	20 Aug 2020 20:20:25

**US3302310**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:51
User entered empty; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:35:18
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	20 Aug 2020 20:20:25

**US3302310**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:51
User entered empty.	Brittany Belcher (b) (4)	20 Aug 2020 20:20:25

US3302310

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:35:18
User entered '62'	Brittany Belcher (b) (4)	20 Aug 2020 20:20:25

**US3302310**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User entered 'bpm'	System	20 Aug 2020 20:20:25

US3302310

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:35:18
User entered '14'	Brittany Belcher (b) (4)	20 Aug 2020 20:20:25

**US3302310**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User entered 'breaths/min'	System	20 Aug 2020 20:20:25

US3302310

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:35:18
User entered '118'	Brittany Belcher (b) (4)	20 Aug 2020 20:20:25

**US3302310**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User entered 'mmHg'	System	20 Aug 2020 20:20:25

US3302310

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:04:51
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:35:18
User entered '72'	Brittany Belcher (b) (4)	20 Aug 2020 20:20:25

**US3302310**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User entered 'mmHg'	System	20 Aug 2020 20:20:25

**US3302310**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18

**US3302310**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18

US3302310

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:22:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	20 Aug 2020 20:20:31

US3302310

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:22:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	30 Sep 2020 21:03:17
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 12:19:41
User entered '20 Aug 2020'	Brittany Belcher (b) (4)	20 Aug 2020 20:20:31

**US3302310**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:22:52**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '20 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	20 Aug 2020 20:20:43

US3302310

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
Query 'Per CDM: Please consider adding contraceptive method under CM form or clarify otherwise. Thank you!' canceled (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:55:49
User opened query 'Per CDM: Please consider adding contraceptive method under CM form or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:55:39
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	20 Aug 2020 20:20:43

**US3302310**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) Brittany Belcher (b) (4)	20 Aug 2020 20:20:43

US3302310

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:22:52

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4)	20 Aug 2020 20:20:43

**US3302310**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) Brittany Belcher (b) (4)	20 Aug 2020 20:20:43

**US3302310**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:22:52**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '0'	(b) (4) Brittany Belcher (b) (4)	20 Aug 2020 20:20:43

**US3302310**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) Brittany Belcher (b) (4)	20 Aug 2020 20:20:43

**US3302310**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:22:52**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '0'	(b) (4) Brittany Belcher (b) (4)	20 Aug 2020 20:20:43

**US3302310**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	20 Aug 2020 20:20:53

**US3302310**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

**Date of test** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '20 Aug 2020'	(b) (4) Brittany Belcher (b) (4)	20 Aug 2020 20:20:53

**US3302310**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Urine (URINE)'	(b) (4) Brittany Belcher (b) (4)	20 Aug 2020 20:20:53

**US3302310**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Negative (NEGATIVE)'	(b) (4) Brittany Belcher (b) (4)	20 Aug 2020 20:20:53

**US3302310**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	20 Aug 2020 20:20:53

**US3302310**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4)	20 Aug 2020 20:20:53

**US3302310**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) Brittany Belcher (b) (4)	20 Aug 2020 20:20:53

**US3302310**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User entered empty.	System	20 Aug 2020 20:20:53

US3302310

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:31
User entered 'No (N)'	Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

US3302310

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:31
User entered 'No (N)'	Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

US3302310

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:31
User entered 'No (N)'	Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

US3302310

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:31
User entered 'No (N)'	Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

US3302310

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:31
User entered 'No (N)'	Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

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[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)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:31
User entered 'No (N)'	Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

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Folder: Screening

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**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)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:31
User entered 'No (N)'	Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

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**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)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:31
User entered 'No (N)'	Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

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[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)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:31
User entered 'No (N)'	Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

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Folder: Screening

Form: Risk of Exposure

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**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)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:31
User entered 'No (N)'	Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

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**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)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:31
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:52

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:31
User entered 'No (N)'	Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:31
User entered empty.	Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

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**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '0' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 18:46:20
User entered '1'	Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

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Folder: Screening

Form: Risk of Exposure

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:31
User entered '0'	Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:31
User entered '0'	Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

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Form: Risk of Exposure

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[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)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:31
User entered '0'	Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:31
User entered '0'	Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:31
User entered '1' reason for change: Data Entry Error	Brittany Belcher (b) (4)	03 Nov 2020 18:46:20
User entered '0'	Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:52

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '0'	(b) (4) Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:42:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:31
User entered empty.	Brittany Belcher (b) (4)	20 Aug 2020 20:21:18

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	20 Aug 2020 20:22:16

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '20 Aug 2020'	(b) (4)	20 Aug 2020 20:22:16

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Clinic (Clinic)'	(b) (4) Brittany Belcher (b) (4)	20 Aug 2020 20:22:16

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'VISIT1'	System	20 Aug 2020 20:22:16

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:58
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 20:19:24

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:22:52

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:05:58
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 06:02:10
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 06:02:10
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 20:19:24
User entered '106324' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 20:19:24

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:58
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 20:19:24

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:58
User entered 'No (N)'	Brittany Belcher (b) (4)	20 Aug 2020 20:22:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:58
User entered 'No (N)'	Brittany Belcher (b) (4)	20 Aug 2020 20:22:25

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:58
User entered 'No (N)'	Brittany Belcher (b) (4)	20 Aug 2020 20:22:25

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:58
User entered 'No (N)'	Brittany Belcher (b) (4)	20 Aug 2020 20:22:25

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:22:52**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:58
User entered 'No (N)'	Brittany Belcher (b) (4)	20 Aug 2020 20:22:25

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**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:05:58
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 13:05:58
DataPoint set to visible.	System	23 Oct 2020 14:35:44
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:51:28

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:22:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:04:54
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Brittany Belcher (b) (4)	07 Oct 2020 13:36:05
answered with 'done' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:36:01
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 08:36:48
User entered '69' in	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:22:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:36:01
User entered '125' lb	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:22:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:04:54
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Brittany Belcher (b) (4)	07 Oct 2020 13:36:05
answered with 'done' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:36:01
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 08:36:48
User entered '69' in	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:22:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:36:01
User entered '125' lb	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User accepted default value 'Pre-Dose (PREDOSE)'	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	10 Nov 2020 21:06:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:36:01
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered '20 Aug 2020' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:36:01
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered '16:07' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:36:01
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered '20 Aug 2020 16:07'	System	07 Oct 2020 13:36:01
User entered empty.	System	21 Aug 2020 11:44:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered '98.7' F reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:36:01
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered 'Oral (Oral)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:36:01
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered '62' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:36:01
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'bpm'	System	07 Oct 2020 13:36:01
User entered empty.	System	21 Aug 2020 11:44:49

US3302310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered '14' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:36:01
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'breaths/min'	System	07 Oct 2020 13:36:01
User entered empty.	System	21 Aug 2020 11:44:49

US3302310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered '118' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:36:01
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

US3302310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'mmHg'	System	07 Oct 2020 13:36:01
User entered empty.	System	21 Aug 2020 11:44:49

US3302310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered '72' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:36:01
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

US3302310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'mmHg'	System	07 Oct 2020 13:36:01
User entered empty.	System	21 Aug 2020 11:44:49

US3302310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:22:52

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:04:54
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Brittany Belcher (b) (4)	07 Oct 2020 13:36:05
answered with 'done' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:36:01
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 08:36:48
User entered '69' in	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

US3302310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:22:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 13:36:01
User entered '125' lb	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

US3302310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User accepted default value 'Post-Dose (POSTDOSE)'	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

US3302310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered '20 Aug 2020'	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered '16:57'	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered '20 Aug 2020 16:57'	System	21 Aug 2020 11:44:49

US3302310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered '98.7' F	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered '62'	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'bpm'	System	21 Aug 2020 11:44:49

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered '18'	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'breaths/min'	System	21 Aug 2020 11:44:49

US3302310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered '101'	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'mmHg'	System	21 Aug 2020 11:44:49

US3302310

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:06:13
User entered '68'	Brittany Belcher (b) (4)	21 Aug 2020 11:44:49

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'mmHg'	System	21 Aug 2020 11:44:49

US3302310

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:22:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'No (N)'	(b) (4)	21 Aug 2020 11:44:54

US3302310

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:22:52

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4)	21 Aug 2020 11:44:54

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'No (N)'	(b) (4)	21 Aug 2020 11:45:00

US3302310

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:22:52

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) Brittany Belcher (b) (4)	21 Aug 2020 11:45:00

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4)	21 Aug 2020 11:45:00

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) Brittany Belcher (b) (4)	21 Aug 2020 11:45:00

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	21 Aug 2020 11:45:00

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) Brittany Belcher (b) (4)	21 Aug 2020 11:45:00

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) Brittany Belcher (b) (4)	21 Aug 2020 11:45:00

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered empty.	System	21 Aug 2020 11:45:00

US3302310

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:22:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:18
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	20 Aug 2020 20:28:52

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:18
User entered empty.	Brittany Belcher (b) (4)	20 Aug 2020 20:28:52

US3302310

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:18
User entered empty.	Brittany Belcher (b) (4)	20 Aug 2020 20:28:52

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 20:28:52

US3302310

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:22:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:18
User entered '20 Aug 2020'	Brittany Belcher (b) (4)	20 Aug 2020 20:28:52

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:18
User entered '16:27'	Brittany Belcher (b) (4)	20 Aug 2020 20:28:52

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered '20 Aug 2020 16:27'	System	20 Aug 2020 20:28:52

US3302310

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:18
User entered 'Left Arm (LEFT ARM)'	Brittany Belcher (b) (4)	20 Aug 2020 20:28:52

US3302310

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:18
User entered 'ONCE'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 20:28:52

US3302310

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	21 Aug 2020 11:45:10

US3302310

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '20 Aug 2020'	(b) (4)	21 Aug 2020 11:45:10

US3302310

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '16:13'	(b) (4)	21 Aug 2020 11:45:10

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered '20 Aug 2020 16:13'	System	21 Aug 2020 11:45:10

US3302310

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:22:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '20 Aug 2020'	(b) (4)	21 Aug 2020 11:45:33

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brittany Belcher (b) (4)	21 Aug 2020 11:45:33

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	21 Aug 2020 11:45:33

US3302310

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:22:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '16:10' reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	21 Aug 2020 11:45:42
User entered '16:13'	Brittany Belcher (b) (4)	21 Aug 2020 11:45:33

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered '20 Aug 2020 16:10'	System	21 Aug 2020 11:45:42
User entered '20 Aug 2020 16:13'	System	21 Aug 2020 11:45:33

US3302310

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:22:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brittany Belcher (b) (4)	21 Aug 2020 11:45:33

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Wendy Taylor (b) (4)	20 Oct 2020 20:02:40
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Aug 2020 11:45:33

US3302310

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:22:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty; reason for change Data Entry Error	(b) (4) Wendy Taylor (b) (4)	20 Oct 2020 20:02:40
User entered '16:10' reason for change: Data Entry Error	Brittany Belcher (b) (4)	21 Aug 2020 11:45:42
User entered '16:13'	Brittany Belcher (b) (4)	21 Aug 2020 11:45:33

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered empty.	System	20 Oct 2020 20:02:40
User entered '20 Aug 2020 16:10'	System	21 Aug 2020 11:45:42
User entered '20 Aug 2020 16:13'	System	21 Aug 2020 11:45:33

US3302310

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	21 Aug 2020 11:45:48

**US3302310**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'I'	System	21 Aug 2020 11:45:48

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 20:28:52

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T16:47:56', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'b5ddd33f-6462-4e74-af5b-c251b0715b17'	System	20 Aug 2020 20:48:18
User entered 'Yes (Y)'	System	20 Aug 2020 20:48:18

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T16:48:04', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'b5ddd33f-6462-4e74-af5b-c251b0715b17' User entered '98.7'	System	20 Aug 2020 20:48:18
	System	20 Aug 2020 20:48:18

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T16:48:07', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'b5ddd33f-6462-4e74-af5b-c251b0715b17'	System	20 Aug 2020 20:48:18
User entered 'No (N)'	System	20 Aug 2020 20:48:18

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T16:48:13', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'b5ddd33f-6462-4e74-af5b-c251b0715b17' User entered '20 Aug 2020 16:48'	System	20 Aug 2020 20:48:18
	System	20 Aug 2020 20:48:18

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '20 Aug 2020 16:47'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '20 Aug 2020 19:17'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T20:17:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6b6d4939-ca1b-4589-acd9-13ea033e4ccb' User entered 'Yes (Y)'	System	21 Aug 2020 00:17:41
	System	21 Aug 2020 00:17:41

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T20:17:21', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6b6d4939-ca1b-4589-acd9-13ea033e4ccb' User entered '97.5'	System	21 Aug 2020 00:17:41
	System	21 Aug 2020 00:17:41

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T20:17:24', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6b6d4939-ca1b-4589-acd9-13ea033e4ccb' User entered 'No (N)'	System	21 Aug 2020 00:17:41
	System	21 Aug 2020 00:17:41

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T20:17:38', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6b6d4939-ca1b-4589-acd9-13ea033e4ccb' User entered '20 Aug 2020 20:17'	System	21 Aug 2020 00:17:41
	System	21 Aug 2020 00:17:41

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '20 Aug 2020 20:12'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 2'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-21T16:52:50', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '39859c88-c95d-4da7-ad15-3fcfa4e9fef9' User entered 'Yes (Y)'	System	21 Aug 2020 20:53:05
	System	21 Aug 2020 20:53:05

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-21T16:52:54', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '39859c88-c95d-4da7-ad15-3fcfa4e9fef9' User entered '97.3'	System	21 Aug 2020 20:53:05
	System	21 Aug 2020 20:53:05

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-21T16:52:57', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '39859c88-c95d-4da7-ad15-3fcfa4e9fef9'	System	21 Aug 2020 20:53:05
User entered 'No (N)'	System	21 Aug 2020 20:53:05

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-21T16:53:01', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '39859c88-c95d-4da7-ad15-3fcfa4e9fef9' User entered '21 Aug 2020 16:53'	System	21 Aug 2020 20:53:05
	System	21 Aug 2020 20:53:05

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 3'	System	20 Aug 2020 20:28:52

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-22T17:38:28', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'dea5921a-b000-4001-98d4-d77cd5cda0a6' User entered 'Yes (Y)'	System	22 Aug 2020 21:38:45
	System	22 Aug 2020 21:38:45

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-22T17:38:32', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'dea5921a-b000-4001-98d4-d77cd5cda0a6' User entered '97.1'	System	22 Aug 2020 21:38:45
	System	22 Aug 2020 21:38:45

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-22T17:38:34', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'dea5921a-b000-4001-98d4-d77cd5cda0a6' User entered 'No (N)'	System	22 Aug 2020 21:38:45
	System	22 Aug 2020 21:38:45

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-22T17:38:43', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'dea5921a-b000-4001-98d4-d77cd5cda0a6' User entered '22 Aug 2020 17:38'	System	22 Aug 2020 21:38:45
	System	22 Aug 2020 21:38:45

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 4'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-23T16:01:01', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '3ab4d00b-12be-4665-8c52-57f1d465b730' User entered 'Yes (Y)'	System	23 Aug 2020 20:01:24
	System	23 Aug 2020 20:01:24

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-23T16:01:06', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '3ab4d00b-12be-4665-8c52-57f1d465b730' User entered '97.6'	System	23 Aug 2020 20:01:24
	System	23 Aug 2020 20:01:24

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-23T16:01:08', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '3ab4d00b-12be-4665-8c52-57f1d465b730' User entered 'Yes (Y)'	System	23 Aug 2020 20:01:24
	System	23 Aug 2020 20:01:24

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:52

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'done' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 15:35:53
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-23T16:01:14', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '3ab4d00b-12be-4665-8c52-57f1d465b730' User entered '1'	Brittany Belcher (b) (4)	28 Oct 2020 17:14:14
	System	23 Aug 2020 20:01:24
	System	23 Aug 2020 20:01:24
	System	23 Aug 2020 20:01:24

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-23T16:01:14', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '3ab4d00b-12be-4665-8c52-57f1d465b730' User entered '0'	System	23 Aug 2020 20:01:24
	System	23 Aug 2020 20:01:24

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-23T16:01:21', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '3ab4d00b-12be-4665-8c52-57f1d465b730' User entered '23 Aug 2020 16:01'	System	23 Aug 2020 20:01:24
	System	23 Aug 2020 20:01:24

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 5'	System	20 Aug 2020 20:28:52

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-24T18:08:28', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '807616f8-2d64-4850-8cf3-e797bf7bb6ae' User entered 'Yes (Y)'	System	24 Aug 2020 22:08:42
	System	24 Aug 2020 22:08:42

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-24T18:08:31', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '807616f8-2d64-4850-8cf3-e797bf7bb6ae' User entered '97.2'	System	24 Aug 2020 22:08:42
	System	24 Aug 2020 22:08:42

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-24T18:08:32', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '807616f8-2d64-4850-8cf3-e797bf7bb6ae' User entered 'Yes (Y)'	System	24 Aug 2020 22:08:42
	System	24 Aug 2020 22:08:42

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:52

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'done' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 15:35:57
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-24T18:08:35', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '807616f8-2d64-4850-8cf3-e797bf7bb6ae' User entered '1'	Brittany Belcher (b) (4)	28 Oct 2020 17:14:20
	System	24 Aug 2020 22:08:42
	System	24 Aug 2020 22:08:42
	System	24 Aug 2020 22:08:42

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:52

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-24T18:08:35', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '807616f8-2d64-4850-8cf3-e797bf7bb6ae' User entered '0'	System	24 Aug 2020 22:08:42
	System	24 Aug 2020 22:08:42

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-24T18:08:39', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '807616f8-2d64-4850-8cf3-e797bf7bb6ae' User entered '24 Aug 2020 18:08'	System	24 Aug 2020 22:08:42
	System	24 Aug 2020 22:08:42

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 6'	System	20 Aug 2020 20:28:52

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-25T18:18:17', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '85eb2891-39a2-4fd2-b744-a271c333c549'	System	25 Aug 2020 22:18:38
User entered 'Yes (Y)'	System	25 Aug 2020 22:18:38

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-25T18:18:22', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '85eb2891-39a2-4fd2-b744-a271c333c549' User entered '97.5'	System	25 Aug 2020 22:18:38
	System	25 Aug 2020 22:18:38

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-25T18:18:24', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '85eb2891-39a2-4fd2-b744-a271c333c549'	System	25 Aug 2020 22:18:38
User entered 'No (N)'	System	25 Aug 2020 22:18:38

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-25T18:18:34', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '85eb2891-39a2-4fd2-b744-a271c333c549' User entered '25 Aug 2020 18:18'	System	25 Aug 2020 22:18:38
	System	25 Aug 2020 22:18:38

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 7'	System	20 Aug 2020 20:28:52

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-26T19:47:17', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'f46ea4e8-11e2-4e3e-b9bd-84ce6d1ad03c' User entered 'Yes (Y)'	System	26 Aug 2020 23:47:40
	System	26 Aug 2020 23:47:40

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-26T19:47:22', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'f46ea4e8-11e2-4e3e-b9bd-84ce6d1ad03c' User entered '97.6'	System	26 Aug 2020 23:47:40
	System	26 Aug 2020 23:47:40

US3302310

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-26T19:47:24', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'f46ea4e8-11e2-4e3e-b9bd-84ce6d1ad03c'	System	26 Aug 2020 23:47:40
User entered 'No (N)'	System	26 Aug 2020 23:47:40

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-26T19:47:35', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'f46ea4e8-11e2-4e3e-b9bd-84ce6d1ad03c' User entered '26 Aug 2020 19:47'	System	26 Aug 2020 23:47:40
	System	26 Aug 2020 23:47:40

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 20:28:52

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T16:48:23', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '98b2d62b-371e-4741-9913-420f7adfaadb' User entered 'None (1)'	System	20 Aug 2020 20:48:41
	System	20 Aug 2020 20:48:41

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T16:48:25', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '98b2d62b-371e-4741-9913-420f7adfaadb' User entered 'No (N)'	System	20 Aug 2020 20:48:41
	System	20 Aug 2020 20:48:41

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T16:48:30', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '98b2d62b-371e-4741-9913-420f7adfaadb' User entered 'No (N)'	System	20 Aug 2020 20:48:41
	System	20 Aug 2020 20:48:41

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T16:48:34', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '98b2d62b-371e-4741-9913-420f7adfaadb' User entered 'None (1)'	System	20 Aug 2020 20:48:41
	System	20 Aug 2020 20:48:41

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T16:48:39', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '98b2d62b-371e-4741-9913-420f7adfaadb' User entered '20 Aug 2020 16:48'	System	20 Aug 2020 20:48:41
	System	20 Aug 2020 20:48:41

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '20 Aug 2020 16:47'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '20 Aug 2020 19:17'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 20:28:52

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T20:17:42', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'e43f958b-3899-4f20-81e1-e1199cab22ed' User entered 'None (1)'	System	21 Aug 2020 00:18:05
	System	21 Aug 2020 00:18:05

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T20:17:55', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'e43f958b-3899-4f20-81e1-e1199cab22ed' User entered 'No (N)'	System	21 Aug 2020 00:18:05
	System	21 Aug 2020 00:18:05

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T20:17:58', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'e43f958b-3899-4f20-81e1-e1199cab22ed' User entered 'No (N)'	System	21 Aug 2020 00:18:05
	System	21 Aug 2020 00:18:05

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T20:18:01', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'e43f958b-3899-4f20-81e1-e1199cab22ed' User entered 'None (1)'	System	21 Aug 2020 00:18:05
	System	21 Aug 2020 00:18:05

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T20:18:03', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'e43f958b-3899-4f20-81e1-e1199cab22ed' User entered '20 Aug 2020 20:18'	System	21 Aug 2020 00:18:05
	System	21 Aug 2020 00:18:05

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '20 Aug 2020 20:12'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 2'	System	20 Aug 2020 20:28:52

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-21T16:51:43', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '3c053a48-d092-4abf-bacc-5d052f714ba1' User entered 'None (1)'	System	21 Aug 2020 20:52:00
	System	21 Aug 2020 20:52:00

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-21T16:51:47', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '3c053a48-d092-4abf-bacc-5d052f714ba1' User entered 'No (N)'	System	21 Aug 2020 20:52:00
	System	21 Aug 2020 20:52:00

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-21T16:51:49', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '3c053a48-d092-4abf-bacc-5d052f714ba1' User entered 'No (N)'	System	21 Aug 2020 20:52:00
	System	21 Aug 2020 20:52:00

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-21T16:51:52', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '3c053a48-d092-4abf-bacc-5d052f714ba1' User entered 'None (1)'	System	21 Aug 2020 20:52:00
	System	21 Aug 2020 20:52:00

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-21T16:51:56', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '3c053a48-d092-4abf-bacc-5d052f714ba1' User entered '21 Aug 2020 16:51'	System	21 Aug 2020 20:52:00
	System	21 Aug 2020 20:52:00

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 3'	System	20 Aug 2020 20:28:52

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-22T17:38:47', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'bef43928-11f0-4ea6-8362-dfc2eeafcf57'	System	22 Aug 2020 21:38:57
User entered 'None (1)'	System	22 Aug 2020 21:38:57

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-22T17:38:49', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'bef43928-11f0-4ea6-8362-dfc2eeafcf57'	System	22 Aug 2020 21:38:57
User entered 'No (N)'	System	22 Aug 2020 21:38:57

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-22T17:38:52', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'bef43928-11f0-4ea6-8362-dfc2eeafcf57'	System	22 Aug 2020 21:38:57
User entered 'No (N)'	System	22 Aug 2020 21:38:57

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-22T17:38:54', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'bef43928-11f0-4ea6-8362-dfc2eeafcf57'	System	22 Aug 2020 21:38:57
User entered 'None (1)'	System	22 Aug 2020 21:38:57

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-22T17:38:56', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'bef43928-11f0-4ea6-8362-dfc2eeafcf57'	System	22 Aug 2020 21:38:57
User entered '22 Aug 2020 17:38'	System	22 Aug 2020 21:38:57

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 4'	System	20 Aug 2020 20:28:52

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-23T16:01:25', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '5092e89b-bd92-4a2e-bcf7-2599af16c7c1' User entered 'None (1)'	System	23 Aug 2020 20:01:35
	System	23 Aug 2020 20:01:35

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-23T16:01:27', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '5092e89b-bd92-4a2e-bcf7-2599af16c7c1' User entered 'No (N)'	System	23 Aug 2020 20:01:35
	System	23 Aug 2020 20:01:35

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-23T16:01:28', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '5092e89b-bd92-4a2e-bcf7-2599af16c7c1' User entered 'No (N)'	System	23 Aug 2020 20:01:35
	System	23 Aug 2020 20:01:35

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-23T16:01:30', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '5092e89b-bd92-4a2e-bcf7-2599af16c7c1' User entered 'None (1)'	System	23 Aug 2020 20:01:35
	System	23 Aug 2020 20:01:35

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-23T16:01:33', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '5092e89b-bd92-4a2e-bcf7-2599af16c7c1' User entered '23 Aug 2020 16:01'	System	23 Aug 2020 20:01:35
	System	23 Aug 2020 20:01:35

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 5'	System	20 Aug 2020 20:28:52

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-24T18:08:42', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '0252c0fe-7eed-447d-a586-fb116d2a34ff'	System	24 Aug 2020 22:08:52
User entered 'None (1)'	System	24 Aug 2020 22:08:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-24T18:08:43', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '0252c0fe-7eed-447d-a586-fb116d2a34ff' User entered 'No (N)'	System	24 Aug 2020 22:08:52
	System	24 Aug 2020 22:08:52

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-24T18:08:44', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '0252c0fe-7eed-447d-a586-fb116d2a34ff'	System	24 Aug 2020 22:08:52
User entered 'No (N)'	System	24 Aug 2020 22:08:52

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-24T18:08:46', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '0252c0fe-7eed-447d-a586-fb116d2a34ff'	System	24 Aug 2020 22:08:52
User entered 'None (1)'	System	24 Aug 2020 22:08:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-24T18:08:49', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '0252c0fe-7eed-447d-a586-fb116d2a34ff' User entered '24 Aug 2020 18:08'	System	24 Aug 2020 22:08:52
	System	24 Aug 2020 22:08:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 6'	System	20 Aug 2020 20:28:52

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-25T18:18:37', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '723f8620-fb20-461d-96cd-3b77668992b2'	System	25 Aug 2020 22:18:55
User entered 'None (1)'	System	25 Aug 2020 22:18:55

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-25T18:18:39', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '723f8620-fb20-461d-96cd-3b77668992b2' User entered 'No (N)'	System	25 Aug 2020 22:18:55
	System	25 Aug 2020 22:18:55

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-25T18:18:41', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '723f8620-fb20-461d-96cd-3b77668992b2' User entered 'No (N)'	System	25 Aug 2020 22:18:55
	System	25 Aug 2020 22:18:55

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-25T18:18:46', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '723f8620-fb20-461d-96cd-3b77668992b2' User entered 'None (1)'	System	25 Aug 2020 22:18:55
	System	25 Aug 2020 22:18:55

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-25T18:18:52', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '723f8620-fb20-461d-96cd-3b77668992b2' User entered '25 Aug 2020 18:18'	System	25 Aug 2020 22:18:55
	System	25 Aug 2020 22:18:55

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 7'	System	20 Aug 2020 20:28:52

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-26T19:47:39', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8fcfd2cc-8310-48a6-ac2f-d869c5e637f4'	System	26 Aug 2020 23:47:48
User entered 'None (1)'	System	26 Aug 2020 23:47:48

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-26T19:47:40', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8fcfd2cc-8310-48a6-ac2f-d869c5e637f4' User entered 'No (N)'	System	26 Aug 2020 23:47:48
	System	26 Aug 2020 23:47:48

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-26T19:47:42', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8fcfd2cc-8310-48a6-ac2f-d869c5e637f4'	System	26 Aug 2020 23:47:48
User entered 'No (N)'	System	26 Aug 2020 23:47:48

US3302310

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-26T19:47:43', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8fcfd2cc-8310-48a6-ac2f-d869c5e637f4' User entered 'None (1)'	System	26 Aug 2020 23:47:48
	System	26 Aug 2020 23:47:48

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-26T19:47:46', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8fcfd2cc-8310-48a6-ac2f-d869c5e637f4'	System	26 Aug 2020 23:47:48
User entered '26 Aug 2020 19:47'	System	26 Aug 2020 23:47:48

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T16:48:50', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '70197ce4-4478-434c-8d13-443eabbd7c45' User entered 'None (0)'	System	20 Aug 2020 20:49:10
	System	20 Aug 2020 20:49:10

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T16:48:52', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '70197ce4-4478-434c-8d13-443eabbd7c45' User entered 'None (0)'	System	20 Aug 2020 20:49:10
	System	20 Aug 2020 20:49:10

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T16:48:54', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '70197ce4-4478-434c-8d13-443eabbd7c45' User entered 'None (0)'	System	20 Aug 2020 20:49:10
	System	20 Aug 2020 20:49:10

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T16:48:57', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '70197ce4-4478-434c-8d13-443eabbd7c45' User entered 'None (0)'	System	20 Aug 2020 20:49:10
	System	20 Aug 2020 20:49:10

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T16:48:58', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '70197ce4-4478-434c-8d13-443eabbd7c45' User entered 'None (0)'	System	20 Aug 2020 20:49:10
	System	20 Aug 2020 20:49:10

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T16:49:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '70197ce4-4478-434c-8d13-443eabbd7c45' User entered 'None (0)'	System	20 Aug 2020 20:49:10
	System	20 Aug 2020 20:49:10

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T16:49:04', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '70197ce4-4478-434c-8d13-443eabbd7c45' User entered 'No (N)'	System	20 Aug 2020 20:49:10
	System	20 Aug 2020 20:49:10

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T16:49:06', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '70197ce4-4478-434c-8d13-443eabbd7c45' User entered '20 Aug 2020 16:49'	System	20 Aug 2020 20:49:10
	System	20 Aug 2020 20:49:10

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '20 Aug 2020 16:47'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '20 Aug 2020 19:17'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T20:18:11', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '320555a3-43c5-4c10-b8da-bdd2692cdc01' User entered 'None (0)'	System	21 Aug 2020 00:18:29
	System	21 Aug 2020 00:18:29

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T20:18:14', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '320555a3-43c5-4c10-b8da-bdd2692cdc01' User entered 'None (0)'	System	21 Aug 2020 00:18:29
	System	21 Aug 2020 00:18:29

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T20:18:16', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '320555a3-43c5-4c10-b8da-bdd2692cdc01' User entered 'None (0)'	System	21 Aug 2020 00:18:29
	System	21 Aug 2020 00:18:29

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T20:18:18', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '320555a3-43c5-4c10-b8da-bdd2692cdc01' User entered 'None (0)'	System	21 Aug 2020 00:18:29
	System	21 Aug 2020 00:18:29

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T20:18:19', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '320555a3-43c5-4c10-b8da-bdd2692cdc01' User entered 'None (0)'	System	21 Aug 2020 00:18:29
	System	21 Aug 2020 00:18:29

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T20:18:22', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '320555a3-43c5-4c10-b8da-bdd2692cdc01' User entered 'None (0)'	System	21 Aug 2020 00:18:29
	System	21 Aug 2020 00:18:29

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T20:18:24', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '320555a3-43c5-4c10-b8da-bdd2692cdc01' User entered 'No (N)'	System	21 Aug 2020 00:18:29
	System	21 Aug 2020 00:18:29

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-20T20:18:27', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '320555a3-43c5-4c10-b8da-bdd2692cdc01' User entered '20 Aug 2020 20:18'	System	21 Aug 2020 00:18:29
	System	21 Aug 2020 00:18:29

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '20 Aug 2020 20:12'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 2'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-21T16:52:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'cf1a054b-4624-4533-950c-b65594c74985' User entered 'None (0)'	System	21 Aug 2020 20:52:21
	System	21 Aug 2020 20:52:21

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-21T16:52:01', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'cf1a054b-4624-4533-950c-b65594c74985' User entered 'None (0)'	System	21 Aug 2020 20:52:21
	System	21 Aug 2020 20:52:21

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-21T16:52:05', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'cf1a054b-4624-4533-950c-b65594c74985' User entered 'None (0)'	System	21 Aug 2020 20:52:21
	System	21 Aug 2020 20:52:21

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-21T16:52:06', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'cf1a054b-4624-4533-950c-b65594c74985' User entered 'None (0)'	System	21 Aug 2020 20:52:21
	System	21 Aug 2020 20:52:21

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-21T16:52:10', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'cf1a054b-4624-4533-950c-b65594c74985' User entered 'None (0)'	System	21 Aug 2020 20:52:21
	System	21 Aug 2020 20:52:21

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-21T16:52:12', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'cf1a054b-4624-4533-950c-b65594c74985' User entered 'None (0)'	System	21 Aug 2020 20:52:21
	System	21 Aug 2020 20:52:21

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-21T16:52:14', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'cf1a054b-4624-4533-950c-b65594c74985' User entered 'No (N)'	System	21 Aug 2020 20:52:21
	System	21 Aug 2020 20:52:21

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-21T16:52:19', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'cf1a054b-4624-4533-950c-b65594c74985' User entered '21 Aug 2020 16:52'	System	21 Aug 2020 20:52:21
	System	21 Aug 2020 20:52:21

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 3'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-22T17:39:03', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8325050a-115a-4858-a132-0f2b8f2f1338' User entered 'None (0)'	System	22 Aug 2020 21:39:24
	System	22 Aug 2020 21:39:24

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-22T17:39:07', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8325050a-115a-4858-a132-0f2b8f2f1338' User entered 'None (0)'	System	22 Aug 2020 21:39:24
	System	22 Aug 2020 21:39:24

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-22T17:39:09', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8325050a-115a-4858-a132-0f2b8f2f1338' User entered 'None (0)'	System	22 Aug 2020 21:39:24
	System	22 Aug 2020 21:39:24

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-22T17:39:10', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8325050a-115a-4858-a132-0f2b8f2f1338' User entered 'None (0)'	System	22 Aug 2020 21:39:24
	System	22 Aug 2020 21:39:24

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-22T17:39:13', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8325050a-115a-4858-a132-0f2b8f2f1338' User entered 'None (0)'	System	22 Aug 2020 21:39:24
	System	22 Aug 2020 21:39:24

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-22T17:39:15', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8325050a-115a-4858-a132-0f2b8f2f1338' User entered 'None (0)'	System	22 Aug 2020 21:39:24
	System	22 Aug 2020 21:39:24

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-22T17:39:17', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8325050a-115a-4858-a132-0f2b8f2f1338' User entered 'No (N)'	System	22 Aug 2020 21:39:24
	System	22 Aug 2020 21:39:24

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-22T17:39:22', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8325050a-115a-4858-a132-0f2b8f2f1338' User entered '22 Aug 2020 17:39'	System	22 Aug 2020 21:39:24
	System	22 Aug 2020 21:39:24

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 4'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-23T16:01:36', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '593cd4b8-db9e-4b4f-ab53-93e8c5bba742' User entered 'None (0)'	System	23 Aug 2020 20:01:51
	System	23 Aug 2020 20:01:51

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-23T16:01:38', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '593cd4b8-db9e-4b4f-ab53-93e8c5bba742' User entered 'None (0)'	System	23 Aug 2020 20:01:51
	System	23 Aug 2020 20:01:51

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-23T16:01:40', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '593cd4b8-db9e-4b4f-ab53-93e8c5bba742' User entered 'None (0)'	System	23 Aug 2020 20:01:51
	System	23 Aug 2020 20:01:51

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-23T16:01:42', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '593cd4b8-db9e-4b4f-ab53-93e8c5bba742' User entered 'None (0)'	System	23 Aug 2020 20:01:51
	System	23 Aug 2020 20:01:51

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-23T16:01:43', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '593cd4b8-db9e-4b4f-ab53-93e8c5bba742' User entered 'None (0)'	System	23 Aug 2020 20:01:51
	System	23 Aug 2020 20:01:51

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-23T16:01:45', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '593cd4b8-db9e-4b4f-ab53-93e8c5bba742' User entered 'None (0)'	System	23 Aug 2020 20:01:51
	System	23 Aug 2020 20:01:51

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-23T16:01:47', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '593cd4b8-db9e-4b4f-ab53-93e8c5bba742' User entered 'No (N)'	System	23 Aug 2020 20:01:51
	System	23 Aug 2020 20:01:51

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-23T16:01:49', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '593cd4b8-db9e-4b4f-ab53-93e8c5bba742' User entered '23 Aug 2020 16:01'	System	23 Aug 2020 20:01:51
	System	23 Aug 2020 20:01:51

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 5'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-24T18:08:52', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'dfbf6782-3bc6-431d-8ae1-4e1c368f67c9' User entered 'None (0)'	System	24 Aug 2020 22:09:08
	System	24 Aug 2020 22:09:08

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-24T18:08:53', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'dfbf6782-3bc6-431d-8ae1-4e1c368f67c9' User entered 'None (0)'	System	24 Aug 2020 22:09:08
	System	24 Aug 2020 22:09:08

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-24T18:08:54', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'dfbf6782-3bc6-431d-8ae1-4e1c368f67c9' User entered 'None (0)'	System	24 Aug 2020 22:09:08
	System	24 Aug 2020 22:09:08

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-24T18:08:56', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'dfbf6782-3bc6-431d-8ae1-4e1c368f67c9' User entered 'None (0)'	System	24 Aug 2020 22:09:08
	System	24 Aug 2020 22:09:08

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-24T18:08:57', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'dfbf6782-3bc6-431d-8ae1-4e1c368f67c9' User entered 'None (0)'	System	24 Aug 2020 22:09:08
	System	24 Aug 2020 22:09:08

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-24T18:08:59', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'dfbf6782-3bc6-431d-8ae1-4e1c368f67c9' User entered 'None (0)'	System	24 Aug 2020 22:09:08
	System	24 Aug 2020 22:09:08

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-24T18:09:01', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'dfbf6782-3bc6-431d-8ae1-4e1c368f67c9'	System	24 Aug 2020 22:09:08
User entered 'No (N)'	System	24 Aug 2020 22:09:08

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-24T18:09:04', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'dfbf6782-3bc6-431d-8ae1-4e1c368f67c9' User entered '24 Aug 2020 18:09'	System	24 Aug 2020 22:09:08
	System	24 Aug 2020 22:09:08

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 6'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-25T18:18:56', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '247793b4-d535-4b49-86d6-6365b9d37ec4' User entered 'None (0)'	System	25 Aug 2020 22:19:20
	System	25 Aug 2020 22:19:20

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-25T18:18:57', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '247793b4-d535-4b49-86d6-6365b9d37ec4' User entered 'None (0)'	System	25 Aug 2020 22:19:20
	System	25 Aug 2020 22:19:20

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-25T18:18:59', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '247793b4-d535-4b49-86d6-6365b9d37ec4' User entered 'None (0)'	System	25 Aug 2020 22:19:20
	System	25 Aug 2020 22:19:20

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-25T18:19:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '247793b4-d535-4b49-86d6-6365b9d37ec4' User entered 'None (0)'	System	25 Aug 2020 22:19:20
	System	25 Aug 2020 22:19:20

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-25T18:19:02', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '247793b4-d535-4b49-86d6-6365b9d37ec4' User entered 'None (0)'	System	25 Aug 2020 22:19:20
	System	25 Aug 2020 22:19:20

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-25T18:19:04', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '247793b4-d535-4b49-86d6-6365b9d37ec4' User entered 'None (0)'	System	25 Aug 2020 22:19:20
	System	25 Aug 2020 22:19:20

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-25T18:19:07', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '247793b4-d535-4b49-86d6-6365b9d37ec4' User entered 'No (N)'	System	25 Aug 2020 22:19:20
	System	25 Aug 2020 22:19:20

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-25T18:19:15', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '247793b4-d535-4b49-86d6-6365b9d37ec4' User entered '25 Aug 2020 18:19'	System	25 Aug 2020 22:19:20
	System	25 Aug 2020 22:19:20

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 7'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-26T19:47:52', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'e9df0f76-0d5d-47a9-bf07-2ad5bb6ee54f' User entered 'None (0)'	System	26 Aug 2020 23:48:09
	System	26 Aug 2020 23:48:09

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-26T19:47:53', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'e9df0f76-0d5d-47a9-bf07-2ad5bb6ee54f' User entered 'None (0)'	System	26 Aug 2020 23:48:09
	System	26 Aug 2020 23:48:09

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-26T19:47:55', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'e9df0f76-0d5d-47a9-bf07-2ad5bb6ee54f' User entered 'None (0)'	System	26 Aug 2020 23:48:09
	System	26 Aug 2020 23:48:09

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-26T19:47:57', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'e9df0f76-0d5d-47a9-bf07-2ad5bb6ee54f' User entered 'None (0)'	System	26 Aug 2020 23:48:09
	System	26 Aug 2020 23:48:09

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-26T19:47:58', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'e9df0f76-0d5d-47a9-bf07-2ad5bb6ee54f' User entered 'None (0)'	System	26 Aug 2020 23:48:09
	System	26 Aug 2020 23:48:09

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-26T19:48:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'e9df0f76-0d5d-47a9-bf07-2ad5bb6ee54f' User entered 'None (0)'	System	26 Aug 2020 23:48:09
	System	26 Aug 2020 23:48:09

US3302310

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-26T19:48:02', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'e9df0f76-0d5d-47a9-bf07-2ad5bb6ee54f' User entered 'No (N)'	System	26 Aug 2020 23:48:09
	System	26 Aug 2020 23:48:09

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-08-26T19:48:06', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'e9df0f76-0d5d-47a9-bf07-2ad5bb6ee54f' User entered '26 Aug 2020 19:48'	System	26 Aug 2020 23:48:09
	System	26 Aug 2020 23:48:09

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	brittany cooksey (b) (4)	31 Aug 2020 19:33:12

US3302310

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User closed query 'Per CDM re-query: Thank you for your answer. However, Day 8 "Safety call" was 11 days after injection. Please review dates or clarify why subject received call later than needed. Thank you!' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 07:14:03
Query 'Per CDM re-query: Thank you for your answer. However, Day 8 "Safety call" was 11 days after injection. Please review dates or clarify why subject received call later than needed. Thank you!' answered with 'completed at later date inn error' (Site from DM).	brittany cooksey (b) (4)	06 Nov 2020 17:47:08
User opened query 'Per CDM re-query: Thank you for your answer. However, Day 8 "Safety call" was 11 days after injection. Please review dates or clarify why subject received call later than needed. Thank you!' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 07:34:38
User closed query 'Per CDM Re-query: Site response noted, however, please confirm Safety Call Day 8 is 31Aug2020, and Exposure is 20Aug2020. Per Protocol, all participants will receive Safety Calls on Day 8, Day 15, Day 22, Day 36, and Day 43 that will serve both to monitor for unsolicited AEs and to monitor for symptoms of COVID-19. Please verify data and update as appropriate, else clarify. Thanks.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 07:34:38
Query 'Per CDM Re-query: Site response noted, however, please confirm Safety Call Day 8 is 31Aug2020, and Exposure is 20Aug2020. Per Protocol, all participants will receive Safety Calls on Day 8, Day 15, Day 22, Day 36, and Day 43 that will serve both to monitor for unsolicited AEs and to monitor for symptoms of COVID-19. Please verify data and update as appropriate, else clarify. Thanks.' answered with 'updated' (Site from DM).	Brittany Belcher (b) (4)	08 Oct 2020 18:51:50

US3302310

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per CDM Re-query: Site response noted, however, please confirm Safety Call Day 8 is 31Aug2020, and Exposure is 20Aug2020. Per Protocol, all participants will receive Safety Calls on Day 8, Day 15, Day 22, Day 36, and Day 43 that will serve both to monitor for unsolicited AEs and to monitor for symptoms of COVID-19. Please verify data and update as appropriate, else clarify. Thanks.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 11:32:52
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 11:32:01
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'entered is correct' (Site from System).	brittany cooksey (b) (4)	31 Aug 2020 19:33:26
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	31 Aug 2020 19:33:12
User entered '31 Aug 2020'	brittany cooksey (b) (4)	31 Aug 2020 19:33:12

US3302310

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) brittany cooksey (b) (4)	31 Aug 2020 19:33:12

**US3302310**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) brittany cooksey (b) (4) (b) (4)	31 Aug 2020 19:33:12

US3302310

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	brittany cooksey (b) (4)	31 Aug 2020 19:33:32

**US3302310**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'I'	System	31 Aug 2020 19:33:32

**US3302310**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	03 Sep 2020 18:05:14

**US3302310**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '3 Sep 2020'	Wendy Taylor (b) (4)	03 Sep 2020 18:05:14

**US3302310**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	03 Sep 2020 18:05:14

**US3302310**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	Wendy Taylor (b) (4)	03 Sep 2020 18:05:14

**US3302310**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	03 Sep 2020 18:05:18

**US3302310**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'I'	System	03 Sep 2020 18:05:18

**US3302310**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	10 Sep 2020 19:32:28

**US3302310**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '10 Sep 2020'	(b) (4) Wendy Taylor (b) (4)	10 Sep 2020 19:32:28

**US3302310**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	10 Sep 2020 19:32:28

**US3302310**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4)	10 Sep 2020 19:32:28
	Wendy Taylor (b) (4)	

**US3302310**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	10 Sep 2020 19:32:57

**US3302310**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'I'	System	10 Sep 2020 19:32:57

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 12:19:41

US3302310

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:22:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
Amendment Manager: User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
	System	17 Sep 2020 00:17:04
Amendment Manager: Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	17 Sep 2020 00:17:04
Amendment Manager: Query text changed to "Visit 2 System Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates."		17 Sep 2020 00:17:04
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	16 Sep 2020 12:19:41
User entered '16 Sep 2020'	Brittany Belcher (b) (4)	16 Sep 2020 12:19:41

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Clinic (Clinic)'	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 12:19:41

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'VISIT2'	System	16 Sep 2020 12:19:41

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User accepted default value 'Pre-Dose (PREDOSE)'	Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 17:17:08
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:11:20
User entered '16 Sep 2020' reason for change: Data Entry Error	Brittany Belcher (b) (4)	16 Sep 2020 17:17:08
User entered empty.	Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User closed query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 16:00:03
Query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you ' answered with 'updated ' (Site from DM).	Wendy Taylor (b) (4)	15 Oct 2020 15:46:41
User entered '07:54' reason for change: Data Entry Error	Wendy Taylor (b) (4)	15 Oct 2020 15:46:35
User opened query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 15:42:13
User entered '7:54' reason for change: Data Entry Error	Brittany Belcher (b) (4)	16 Sep 2020 17:17:08
User entered empty.	Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered '16 Sep 2020 07:54'	System	15 Oct 2020 15:46:35
User entered '16 Sep 2020 7:54'	System	16 Sep 2020 17:17:08
User entered empty.	System	16 Sep 2020 13:58:26

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '97.3' F reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 17:17:08
User entered empty.	Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 17:17:08
User entered empty.	Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '63' reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 17:17:08
User entered empty.	Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'bpm'	System	16 Sep 2020 17:17:08
User entered empty.	System	16 Sep 2020 13:58:26

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '16' reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 17:17:08
User entered empty.	Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'breaths/min'	System	16 Sep 2020 17:17:08
User entered empty.	System	16 Sep 2020 13:58:26

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '111' reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 17:17:08
User entered empty.	Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'mmHg'	System	16 Sep 2020 17:17:08
User entered empty.	System	16 Sep 2020 13:58:26

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '74' reason for change: Data Entry Error	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 17:17:08
User entered empty.	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'mmHg'	System	16 Sep 2020 17:17:08
User entered empty.	System	16 Sep 2020 13:58:26

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User accepted default value 'Post-Dose (POSTDOSE)'	Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '16 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User closed query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 16:00:12
Query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you ' answered with 'updated ' (Site from DM).	Wendy Taylor (b) (4)	15 Oct 2020 15:46:56
User entered '08:43' reason for change: Data Entry Error	Wendy Taylor (b) (4)	15 Oct 2020 15:46:50
User opened query 'Per CDM: Please update time to reflect 24-hour clock format (HH:MM). Thank you ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 15:42:26
User entered '8:43'	Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered '16 Sep 2020 08:43'	System	15 Oct 2020 15:46:50
User entered '16 Sep 2020 8:43'	System	16 Sep 2020 13:58:26

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '97.3' F	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Oral (Oral)'	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '61'	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'bpm'	System	16 Sep 2020 13:58:26

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '16'	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'breaths/min'	System	16 Sep 2020 13:58:26

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '106'	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'mmHg'	System	16 Sep 2020 13:58:26

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '69'	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:58:26

US3302310

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'mmHg'	System	16 Sep 2020 13:58:26

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:22:52**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:58:36

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:22:52**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '16 Sep 2020'	(b) (4)	16 Sep 2020 13:58:36

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:58:46

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

**Date of test** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '16 Sep 2020'	(b) (4)	16 Sep 2020 13:58:46

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Urine (URINE)'	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:58:46

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Negative (NEGATIVE)'	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:58:46

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'No (N)'	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:58:46

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:58:46

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:58:46

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered empty.	System	16 Sep 2020 13:58:46

US3302310

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:22:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:50
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	16 Sep 2020 12:20:02

US3302310

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:22:52

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:50
User entered empty.	Brittany Belcher (b) (4)	16 Sep 2020 12:20:02

US3302310

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:50
User entered empty.	Brittany Belcher (b) (4)	16 Sep 2020 12:20:02

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 12:20:02

US3302310

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:22:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:50
User entered '16 Sep 2020'	Brittany Belcher (b) (4)	16 Sep 2020 12:20:02

US3302310

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:50
User closed query 'Per CDM: Please consider updating the time format to HH:MM, including 2 digits for hour (for example 01:23). ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 20:35:57
Query 'Per CDM: Please consider updating the time format to HH:MM, including 2 digits for hour (for example 01:23). ' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	06 Nov 2020 17:47:47
User entered '08:13' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 17:47:40
User opened query 'Per CDM: Please consider updating the time format to HH:MM, including 2 digits for hour (for example 01:23). ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 17:09:47
User entered '8:13'	Brittany Belcher (b) (4)	16 Sep 2020 12:20:02

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered '16 Sep 2020 08:13'	System	06 Nov 2020 17:47:40
User entered '16 Sep 2020 8:13'	System	16 Sep 2020 12:20:02

US3302310

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:50
User entered 'Left Arm (LEFT ARM)'	Brittany Belcher (b) (4)	16 Sep 2020 12:20:02

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:07:50
User entered 'ONCE'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:59:17

US3302310

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '16 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:59:17

US3302310

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '08:00' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Nov 2020 13:06:18
User entered '8:00'	Brittany Belcher (b) (4)	16 Sep 2020 13:59:17

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered '16 Sep 2020 08:00'	System	09 Nov 2020 13:06:18
User entered '16 Sep 2020 8:00'	System	16 Sep 2020 13:59:17

US3302310

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:22:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '16 Sep 2020'	(b) (4)	16 Sep 2020 13:59:30

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brittany Belcher (b) (4)	16 Sep 2020 13:59:30

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:59:30

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '07:58' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Nov 2020 13:06:26
User entered '7:58'	Brittany Belcher (b) (4)	16 Sep 2020 13:59:30

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered '16 Sep 2020 07:58'	System	09 Nov 2020 13:06:26
User entered '16 Sep 2020 7:58'	System	16 Sep 2020 13:59:30

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brittany Belcher (b) (4)	16 Sep 2020 13:59:30

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:59:30

US3302310

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:22:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '07:58' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Nov 2020 13:06:26
User entered '7:58'	Brittany Belcher (b) (4)	16 Sep 2020 13:59:30

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered '16 Sep 2020 07:58'	System	09 Nov 2020 13:06:26
User entered '16 Sep 2020 7:58'	System	16 Sep 2020 13:59:30

US3302310

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	16 Sep 2020 13:59:34

**US3302310**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered '1'	System	16 Sep 2020 13:59:34

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 12:20:02

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T08:33:09', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '474a5326-3546-4a1c-8beb-d2530f64c4a4' User entered 'Yes (Y)'	System	16 Sep 2020 12:33:22
	System	16 Sep 2020 12:33:22

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T08:33:15', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '474a5326-3546-4a1c-8beb-d2530f64c4a4' User entered '97.3'	System	16 Sep 2020 12:33:22
	System	16 Sep 2020 12:33:22

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T08:33:17', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '474a5326-3546-4a1c-8beb-d2530f64c4a4' User entered 'No (N)'	System	16 Sep 2020 12:33:22
	System	16 Sep 2020 12:33:22

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T08:33:20', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '474a5326-3546-4a1c-8beb-d2530f64c4a4' User entered '16 Sep 2020 08:33'	System	16 Sep 2020 12:33:22
	System	16 Sep 2020 12:33:22

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '16 Sep 2020 08:33'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '16 Sep 2020 11:03'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 12:20:02

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T17:51:22', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6555aef0-41d8-4d54-8570-fb926fa32f2c' User entered 'Yes (Y)'	System	16 Sep 2020 21:51:34
	System	16 Sep 2020 21:51:34

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T17:51:26', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6555aef0-41d8-4d54-8570-fb926fa32f2c' User entered '97.2'	System	16 Sep 2020 21:51:34
	System	16 Sep 2020 21:51:34

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T17:51:29', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6555aef0-41d8-4d54-8570-fb926fa32f2c' User entered 'No (N)'	System	16 Sep 2020 21:51:34
	System	16 Sep 2020 21:51:34

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T17:51:31', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6555aef0-41d8-4d54-8570-fb926fa32f2c' User entered '16 Sep 2020 17:51'	System	16 Sep 2020 21:51:34
	System	16 Sep 2020 21:51:34

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '16 Sep 2020 11:58'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 2'	System	16 Sep 2020 12:20:02

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-17T17:12:46', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '0a777eb0-d926-4982-b006-bc598293b2e9' User entered 'Yes (Y)'	System	17 Sep 2020 21:13:08
	System	17 Sep 2020 21:13:08

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-17T17:12:54', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '0a777eb0-d926-4982-b006-bc598293b2e9' User entered '97.2'	System	17 Sep 2020 21:13:08
	System	17 Sep 2020 21:13:08

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-17T17:12:57', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '0a777eb0-d926-4982-b006-bc598293b2e9' User entered 'No (N)'	System	17 Sep 2020 21:13:08
	System	17 Sep 2020 21:13:08

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-17T17:13:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '0a777eb0-d926-4982-b006-bc598293b2e9' User entered '17 Sep 2020 17:13'	System	17 Sep 2020 21:13:08
	System	17 Sep 2020 21:13:08

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 3'	System	16 Sep 2020 12:20:02

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T07:58:27', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '02937663-2925-4f3c-9148-a8ab4b66eb0f' User entered 'Yes (Y)'	System	19 Sep 2020 11:58:41
	System	19 Sep 2020 11:58:41

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T07:58:32', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '02937663-2925-4f3c-9148-a8ab4b66eb0f' User entered '97.4'	System	19 Sep 2020 11:58:41
	System	19 Sep 2020 11:58:41

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T07:58:34', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '02937663-2925-4f3c-9148-a8ab4b66eb0f' User entered 'No (N)'	System	19 Sep 2020 11:58:41
	System	19 Sep 2020 11:58:41

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T07:58:38', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '02937663-2925-4f3c-9148-a8ab4b66eb0f' User entered '19 Sep 2020 07:58'	System	19 Sep 2020 11:58:41
	System	19 Sep 2020 11:58:41

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 4'	System	16 Sep 2020 12:20:02

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T16:07:28', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'c4a084ea-3108-44e1-886c-5e77e399fd31' User entered 'Yes (Y)'	System	19 Sep 2020 20:07:37
	System	19 Sep 2020 20:07:37

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T16:07:31', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'c4a084ea-3108-44e1-886c-5e77e399fd31' User entered '98.2'	System	19 Sep 2020 20:07:37
	System	19 Sep 2020 20:07:37

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T16:07:33', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'c4a084ea-3108-44e1-886c-5e77e399fd31' User entered 'No (N)'	System	19 Sep 2020 20:07:37
	System	19 Sep 2020 20:07:37

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T16:07:36', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'c4a084ea-3108-44e1-886c-5e77e399fd31' User entered '19 Sep 2020 16:07'	System	19 Sep 2020 20:07:37
	System	19 Sep 2020 20:07:37

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 5'	System	16 Sep 2020 12:20:02

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-20T16:50:56', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6c814613-3db6-459f-a911-25240d7cf7b8' User entered 'Yes (Y)'	System	20 Sep 2020 20:51:07
	System	20 Sep 2020 20:51:07

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-20T16:50:59', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6c814613-3db6-459f-a911-25240d7cf7b8' User entered '97.1'	System	20 Sep 2020 20:51:07
	System	20 Sep 2020 20:51:07

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-20T16:51:02', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6c814613-3db6-459f-a911-25240d7cf7b8' User entered 'No (N)'	System	20 Sep 2020 20:51:07
	System	20 Sep 2020 20:51:07

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-20T16:51:04', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6c814613-3db6-459f-a911-25240d7cf7b8' User entered '20 Sep 2020 16:51'	System	20 Sep 2020 20:51:07
	System	20 Sep 2020 20:51:07

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 6'	System	16 Sep 2020 12:20:02

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-21T19:27:07', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'c2fe2ab9-2200-4524-88e8-966548342369' User entered 'Yes (Y)'	System	21 Sep 2020 23:27:21
	System	21 Sep 2020 23:27:21

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-21T19:27:11', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'c2fe2ab9-2200-4524-88e8-966548342369' User entered '98.8'	System	21 Sep 2020 23:27:21
	System	21 Sep 2020 23:27:21

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-21T19:27:13', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'c2fe2ab9-2200-4524-88e8-966548342369' User entered 'No (N)'	System	21 Sep 2020 23:27:21
	System	21 Sep 2020 23:27:21

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-21T19:27:17', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'c2fe2ab9-2200-4524-88e8-966548342369' User entered '21 Sep 2020 19:27'	System	21 Sep 2020 23:27:21
	System	21 Sep 2020 23:27:21

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 7'	System	16 Sep 2020 12:20:02

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-22T19:12:15', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'd58bb47d-7d85-471a-8b3c-360ccbee9650' User entered 'Yes (Y)'	System	22 Sep 2020 23:12:27
	System	22 Sep 2020 23:12:27

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-22T19:12:19', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'd58bb47d-7d85-471a-8b3c-360ccbee9650' User entered '98.3'	System	22 Sep 2020 23:12:27
	System	22 Sep 2020 23:12:27

US3302310

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-22T19:12:21', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'd58bb47d-7d85-471a-8b3c-360ccbee9650' User entered 'No (N)'	System	22 Sep 2020 23:12:27
	System	22 Sep 2020 23:12:27

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-22T19:12:24', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'd58bb47d-7d85-471a-8b3c-360ccbee9650' User entered '22 Sep 2020 19:12'	System	22 Sep 2020 23:12:27
	System	22 Sep 2020 23:12:27

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 12:20:02

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T08:33:27', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '3650f159-d0b0-4ebd-ba2a-1dc8a44d2682'	System	16 Sep 2020 12:34:00
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 12:34:00

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T08:33:32', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '3650f159-d0b0-4ebd-ba2a-1dc8a44d2682' User entered 'No (N)'	System	16 Sep 2020 12:34:00
	System	16 Sep 2020 12:34:00

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T08:33:43', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '3650f159-d0b0-4ebd-ba2a-1dc8a44d2682' User entered 'No (N)'	System	16 Sep 2020 12:34:00
	System	16 Sep 2020 12:34:00

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T08:33:53', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '3650f159-d0b0-4ebd-ba2a-1dc8a44d2682' User entered 'None (1)'	System	16 Sep 2020 12:34:00
	System	16 Sep 2020 12:34:00

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T08:33:57', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '3650f159-d0b0-4ebd-ba2a-1dc8a44d2682' User entered '16 Sep 2020 08:33'	System	16 Sep 2020 12:34:00
	System	16 Sep 2020 12:34:00

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '16 Sep 2020 08:33'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '16 Sep 2020 11:03'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 12:20:02

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T17:50:48', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'fdd74c87-600e-403c-b349-f56d3bc2f6a6'	System	16 Sep 2020 21:51:19
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 21:51:19

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T17:50:52', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'fdd74c87-600e-403c-b349-f56d3bc2f6a6' User entered 'No (N)'	System	16 Sep 2020 21:51:19
	System	16 Sep 2020 21:51:19

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T17:51:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'fdd74c87-600e-403c-b349-f56d3bc2f6a6' User entered 'No (N)'	System	16 Sep 2020 21:51:19
	System	16 Sep 2020 21:51:19

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T17:51:02', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'fdd74c87-600e-403c-b349-f56d3bc2f6a6'	System	16 Sep 2020 21:51:19
User entered 'None (1)'	System	16 Sep 2020 21:51:19

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T17:51:15', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'fdd74c87-600e-403c-b349-f56d3bc2f6a6'	System	16 Sep 2020 21:51:19
User entered '16 Sep 2020 17:51'	System	16 Sep 2020 21:51:19

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '16 Sep 2020 11:58'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 2'	System	16 Sep 2020 12:20:02

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-17T17:12:01', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '4854f0af-5a46-4302-945b-2f30ed86d533'	System	17 Sep 2020 21:12:11
User entered 'None (1)'	System	17 Sep 2020 21:12:11

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-17T17:12:03', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '4854f0af-5a46-4302-945b-2f30ed86d533'	System	17 Sep 2020 21:12:11
User entered 'No (N)'	System	17 Sep 2020 21:12:11

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-17T17:12:05', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '4854f0af-5a46-4302-945b-2f30ed86d533'	System	17 Sep 2020 21:12:11
User entered 'No (N)'	System	17 Sep 2020 21:12:11

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-17T17:12:07', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '4854f0af-5a46-4302-945b-2f30ed86d533'	System	17 Sep 2020 21:12:11
User entered 'None (1)'	System	17 Sep 2020 21:12:11

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-17T17:12:09', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '4854f0af-5a46-4302-945b-2f30ed86d533' User entered '17 Sep 2020 17:12'	System	17 Sep 2020 21:12:11
	System	17 Sep 2020 21:12:11

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 3'	System	16 Sep 2020 12:20:02

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T07:58:41', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8cafb7c5-b33d-4cac-b49f-6cc2527abf14' User entered 'None (1)'	System	19 Sep 2020 11:58:53
	System	19 Sep 2020 11:58:53

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T07:58:43', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8cafb7c5-b33d-4cac-b49f-6cc2527abf14' User entered 'No (N)'	System	19 Sep 2020 11:58:53
	System	19 Sep 2020 11:58:53

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T07:58:45', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8cafb7c5-b33d-4cac-b49f-6cc2527abf14' User entered 'No (N)'	System	19 Sep 2020 11:58:53
	System	19 Sep 2020 11:58:53

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T07:58:47', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8cafb7c5-b33d-4cac-b49f-6cc2527abf14' User entered 'None (1)'	System	19 Sep 2020 11:58:53
	System	19 Sep 2020 11:58:53

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T07:58:51', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8cafb7c5-b33d-4cac-b49f-6cc2527abf14' User entered '19 Sep 2020 07:58'	System	19 Sep 2020 11:58:53
	System	19 Sep 2020 11:58:53

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 4'	System	16 Sep 2020 12:20:02

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T16:07:39', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8a2ed9e4-7380-40c8-9c0c-9e20a4e7a09e' User entered 'None (1)'	System	19 Sep 2020 20:07:55
	System	19 Sep 2020 20:07:55

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T16:07:41', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8a2ed9e4-7380-40c8-9c0c-9e20a4e7a09e' User entered 'No (N)'	System	19 Sep 2020 20:07:55
	System	19 Sep 2020 20:07:55

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T16:07:42', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8a2ed9e4-7380-40c8-9c0c-9e20a4e7a09e' User entered 'No (N)'	System	19 Sep 2020 20:07:55
	System	19 Sep 2020 20:07:55

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T16:07:44', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8a2ed9e4-7380-40c8-9c0c-9e20a4e7a09e' User entered 'None (1)'	System	19 Sep 2020 20:07:55
	System	19 Sep 2020 20:07:55

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T16:07:52', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '8a2ed9e4-7380-40c8-9c0c-9e20a4e7a09e' User entered '19 Sep 2020 16:07'	System	19 Sep 2020 20:07:55
	System	19 Sep 2020 20:07:55

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 5'	System	16 Sep 2020 12:20:02

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-20T16:51:08', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'c7cf6df3-2262-4fdf-8886-aaed2be64546'	System	20 Sep 2020 20:51:19
User entered 'None (1)'	System	20 Sep 2020 20:51:19

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-20T16:51:09', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'c7cf6df3-2262-4fdf-8886-aaed2be64546' User entered 'No (N)'	System	20 Sep 2020 20:51:19
	System	20 Sep 2020 20:51:19

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-20T16:51:10', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'c7cf6df3-2262-4fdf-8886-aaed2be64546' User entered 'No (N)'	System	20 Sep 2020 20:51:19
	System	20 Sep 2020 20:51:19

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-20T16:51:12', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'c7cf6df3-2262-4fdf-8886-aaed2be64546' User entered 'None (1)'	System	20 Sep 2020 20:51:19
	System	20 Sep 2020 20:51:19

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-20T16:51:14', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'c7cf6df3-2262-4fdf-8886-aaed2be64546' User entered '20 Sep 2020 16:51'	System	20 Sep 2020 20:51:19
	System	20 Sep 2020 20:51:19

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 6'	System	16 Sep 2020 12:20:02

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-21T19:27:22', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'fda6bd72-bf98-42bc-b323-9386cd58309c' User entered 'None (1)'	System	21 Sep 2020 23:27:35
	System	21 Sep 2020 23:27:35

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-21T19:27:24', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'fda6bd72-bf98-42bc-b323-9386cd58309c' User entered 'No (N)'	System	21 Sep 2020 23:27:35
	System	21 Sep 2020 23:27:35

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-21T19:27:26', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'fda6bd72-bf98-42bc-b323-9386cd58309c' User entered 'No (N)'	System	21 Sep 2020 23:27:35
	System	21 Sep 2020 23:27:35

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-21T19:27:28', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'fda6bd72-bf98-42bc-b323-9386cd58309c' User entered 'None (1)'	System	21 Sep 2020 23:27:35
	System	21 Sep 2020 23:27:35

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-21T19:27:31', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'fda6bd72-bf98-42bc-b323-9386cd58309c' User entered '21 Sep 2020 19:27'	System	21 Sep 2020 23:27:35
	System	21 Sep 2020 23:27:35

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 7'	System	16 Sep 2020 12:20:02

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-22T19:12:30', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '526f99a0-671e-450e-a505-55552af715a5' User entered 'None (1)'	System	22 Sep 2020 23:12:42
	System	22 Sep 2020 23:12:42

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:52

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-22T19:12:32', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '526f99a0-671e-450e-a505-55552af715a5' User entered 'No (N)'	System	22 Sep 2020 23:12:42
	System	22 Sep 2020 23:12:42

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-22T19:12:33', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '526f99a0-671e-450e-a505-55552af715a5' User entered 'No (N)'	System	22 Sep 2020 23:12:42
	System	22 Sep 2020 23:12:42

US3302310

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-22T19:12:36', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '526f99a0-671e-450e-a505-55552af715a5' User entered 'None (1)'	System	22 Sep 2020 23:12:42
	System	22 Sep 2020 23:12:42

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-22T19:12:40', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '526f99a0-671e-450e-a505-55552af715a5' User entered '22 Sep 2020 19:12'	System	22 Sep 2020 23:12:42
	System	22 Sep 2020 23:12:42

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T08:34:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '26a25169-55ff-4034-b74d-ceb163053fd1' User entered 'None (0)'	System	16 Sep 2020 12:34:17
	System	16 Sep 2020 12:34:17

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T08:34:02', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '26a25169-55ff-4034-b74d-ceb163053fd1' User entered 'None (0)'	System	16 Sep 2020 12:34:17
	System	16 Sep 2020 12:34:17

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T08:34:04', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '26a25169-55ff-4034-b74d-ceb163053fd1' User entered 'None (0)'	System	16 Sep 2020 12:34:17
	System	16 Sep 2020 12:34:17

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T08:34:05', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '26a25169-55ff-4034-b74d-ceb163053fd1' User entered 'None (0)'	System	16 Sep 2020 12:34:17
	System	16 Sep 2020 12:34:17

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T08:34:07', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '26a25169-55ff-4034-b74d-ceb163053fd1' User entered 'None (0)'	System	16 Sep 2020 12:34:17
	System	16 Sep 2020 12:34:17

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T08:34:09', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '26a25169-55ff-4034-b74d-ceb163053fd1' User entered 'None (0)'	System	16 Sep 2020 12:34:17
	System	16 Sep 2020 12:34:17

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T08:34:11', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '26a25169-55ff-4034-b74d-ceb163053fd1' User entered 'No (N)'	System	16 Sep 2020 12:34:17
	System	16 Sep 2020 12:34:17

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T08:34:14', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '26a25169-55ff-4034-b74d-ceb163053fd1' User entered '16 Sep 2020 08:34'	System	16 Sep 2020 12:34:17
	System	16 Sep 2020 12:34:17

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '16 Sep 2020 08:33'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '16 Sep 2020 11:03'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T17:51:35', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '5cd59597-4efe-446a-8c20-f3d165715a07' User entered 'None (0)'	System	16 Sep 2020 21:51:47
	System	16 Sep 2020 21:51:47

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T17:51:36', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '5cd59597-4efe-446a-8c20-f3d165715a07' User entered 'None (0)'	System	16 Sep 2020 21:51:47
	System	16 Sep 2020 21:51:47

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T17:51:38', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '5cd59597-4efe-446a-8c20-f3d165715a07' User entered 'None (0)'	System	16 Sep 2020 21:51:47
	System	16 Sep 2020 21:51:47

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T17:51:39', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '5cd59597-4efe-446a-8c20-f3d165715a07' User entered 'None (0)'	System	16 Sep 2020 21:51:47
	System	16 Sep 2020 21:51:47

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T17:51:40', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '5cd59597-4efe-446a-8c20-f3d165715a07' User entered 'None (0)'	System	16 Sep 2020 21:51:47
	System	16 Sep 2020 21:51:47

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T17:51:42', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '5cd59597-4efe-446a-8c20-f3d165715a07' User entered 'None (0)'	System	16 Sep 2020 21:51:47
	System	16 Sep 2020 21:51:47

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T17:51:44', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '5cd59597-4efe-446a-8c20-f3d165715a07' User entered 'No (N)'	System	16 Sep 2020 21:51:47
	System	16 Sep 2020 21:51:47

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-16T17:51:46', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '5cd59597-4efe-446a-8c20-f3d165715a07' User entered '16 Sep 2020 17:51'	System	16 Sep 2020 21:51:47
	System	16 Sep 2020 21:51:47

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '16 Sep 2020 11:58'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 2'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-17T17:12:12', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '1aa41fdb-06ae-4515-b0b8-ee652c0a37f9' User entered 'None (0)'	System	17 Sep 2020 21:12:33
	System	17 Sep 2020 21:12:33

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-17T17:12:14', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '1aa41fdb-06ae-4515-b0b8-ee652c0a37f9' User entered 'None (0)'	System	17 Sep 2020 21:12:33
	System	17 Sep 2020 21:12:33

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-17T17:12:16', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '1aa41fdb-06ae-4515-b0b8-ee652c0a37f9' User entered 'None (0)'	System	17 Sep 2020 21:12:33
	System	17 Sep 2020 21:12:33

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-17T17:12:17', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '1aa41fdb-06ae-4515-b0b8-ee652c0a37f9' User entered 'None (0)'	System	17 Sep 2020 21:12:33
	System	17 Sep 2020 21:12:33

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-17T17:12:19', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '1aa41fdb-06ae-4515-b0b8-ee652c0a37f9' User entered 'None (0)'	System	17 Sep 2020 21:12:33
	System	17 Sep 2020 21:12:33

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-17T17:12:21', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '1aa41fdb-06ae-4515-b0b8-ee652c0a37f9' User entered 'None (0)'	System	17 Sep 2020 21:12:33
	System	17 Sep 2020 21:12:33

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-17T17:12:23', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '1aa41fdb-06ae-4515-b0b8-ee652c0a37f9' User entered 'No (N)'	System	17 Sep 2020 21:12:33
	System	17 Sep 2020 21:12:33

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-17T17:12:30', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '1aa41fdb-06ae-4515-b0b8-ee652c0a37f9' User entered '17 Sep 2020 17:12'	System	17 Sep 2020 21:12:33
	System	17 Sep 2020 21:12:33

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 3'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T07:58:53', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6311cf86-df5e-433b-9a81-5aa2452a6280' User entered 'None (0)'	System	19 Sep 2020 11:59:11
	System	19 Sep 2020 11:59:11

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T07:58:55', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6311cf86-df5e-433b-9a81-5aa2452a6280' User entered 'None (0)'	System	19 Sep 2020 11:59:11
	System	19 Sep 2020 11:59:11

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T07:58:57', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6311cf86-df5e-433b-9a81-5aa2452a6280' User entered 'None (0)'	System	19 Sep 2020 11:59:11
	System	19 Sep 2020 11:59:11

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T07:58:58', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6311cf86-df5e-433b-9a81-5aa2452a6280' User entered 'None (0)'	System	19 Sep 2020 11:59:11
	System	19 Sep 2020 11:59:11

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T07:59:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6311cf86-df5e-433b-9a81-5aa2452a6280' User entered 'None (0)'	System	19 Sep 2020 11:59:11
	System	19 Sep 2020 11:59:11

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T07:59:02', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6311cf86-df5e-433b-9a81-5aa2452a6280' User entered 'None (0)'	System	19 Sep 2020 11:59:11
	System	19 Sep 2020 11:59:11

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T07:59:04', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6311cf86-df5e-433b-9a81-5aa2452a6280' User entered 'No (N)'	System	19 Sep 2020 11:59:11
	System	19 Sep 2020 11:59:11

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T07:59:08', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6311cf86-df5e-433b-9a81-5aa2452a6280' User entered '19 Sep 2020 07:59'	System	19 Sep 2020 11:59:11
	System	19 Sep 2020 11:59:11

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 4'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T16:07:58', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '64382b04-c085-4ff7-aa20-cde97bb13cce' User entered 'None (0)'	System	19 Sep 2020 20:08:17
	System	19 Sep 2020 20:08:17

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T16:08:01', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '64382b04-c085-4ff7-aa20-cde97bb13cce' User entered 'None (0)'	System	19 Sep 2020 20:08:17
	System	19 Sep 2020 20:08:17

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T16:08:02', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '64382b04-c085-4ff7-aa20-cde97bb13cce' User entered 'None (0)'	System	19 Sep 2020 20:08:17
	System	19 Sep 2020 20:08:17

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T16:08:04', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '64382b04-c085-4ff7-aa20-cde97bb13cce' User entered 'None (0)'	System	19 Sep 2020 20:08:17
	System	19 Sep 2020 20:08:17

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T16:08:05', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '64382b04-c085-4ff7-aa20-cde97bb13cce' User entered 'None (0)'	System	19 Sep 2020 20:08:17
	System	19 Sep 2020 20:08:17

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T16:08:07', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '64382b04-c085-4ff7-aa20-cde97bb13cce' User entered 'None (0)'	System	19 Sep 2020 20:08:17
	System	19 Sep 2020 20:08:17

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T16:08:11', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '64382b04-c085-4ff7-aa20-cde97bb13cce' User entered 'No (N)'	System	19 Sep 2020 20:08:17
	System	19 Sep 2020 20:08:17

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-19T16:08:15', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '64382b04-c085-4ff7-aa20-cde97bb13cce' User entered '19 Sep 2020 16:08'	System	19 Sep 2020 20:08:17
	System	19 Sep 2020 20:08:17

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 5'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-20T16:51:29', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'abd7e4f8-0e8c-49e0-bb11-e901d450e30c'	System	20 Sep 2020 20:51:45
User entered 'No interference with activity (1)'	System	20 Sep 2020 20:51:45

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-20T16:51:32', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'abd7e4f8-0e8c-49e0-bb11-e901d450e30c' User entered 'None (0)'	System	20 Sep 2020 20:51:45
	System	20 Sep 2020 20:51:45

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-20T16:51:34', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'abd7e4f8-0e8c-49e0-bb11-e901d450e30c' User entered 'None (0)'	System	20 Sep 2020 20:51:45
	System	20 Sep 2020 20:51:45

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-20T16:51:36', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'abd7e4f8-0e8c-49e0-bb11-e901d450e30c' User entered 'None (0)'	System	20 Sep 2020 20:51:45
	System	20 Sep 2020 20:51:45

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-20T16:51:37', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'abd7e4f8-0e8c-49e0-bb11-e901d450e30c' User entered 'None (0)'	System	20 Sep 2020 20:51:45
	System	20 Sep 2020 20:51:45

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-20T16:51:39', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'abd7e4f8-0e8c-49e0-bb11-e901d450e30c' User entered 'None (0)'	System	20 Sep 2020 20:51:45
	System	20 Sep 2020 20:51:45

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-20T16:51:40', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'abd7e4f8-0e8c-49e0-bb11-e901d450e30c' User entered 'No (N)'	System	20 Sep 2020 20:51:45
	System	20 Sep 2020 20:51:45

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-20T16:51:42', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'abd7e4f8-0e8c-49e0-bb11-e901d450e30c' User entered '20 Sep 2020 16:51'	System	20 Sep 2020 20:51:45
	System	20 Sep 2020 20:51:45

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 6'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-21T19:27:35', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '83df83ae-c50b-48e2-b9c9-0778086ae758'	System	21 Sep 2020 23:27:50
User entered 'No interference with activity (1)'	System	21 Sep 2020 23:27:50

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-21T19:27:37', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '83df83ae-c50b-48e2-b9c9-0778086ae758' User entered 'None (0)'	System	21 Sep 2020 23:27:50
	System	21 Sep 2020 23:27:50

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-21T19:27:38', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '83df83ae-c50b-48e2-b9c9-0778086ae758' User entered 'None (0)'	System	21 Sep 2020 23:27:50
	System	21 Sep 2020 23:27:50

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-21T19:27:40', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '83df83ae-c50b-48e2-b9c9-0778086ae758' User entered 'None (0)'	System	21 Sep 2020 23:27:50
	System	21 Sep 2020 23:27:50

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-21T19:27:42', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '83df83ae-c50b-48e2-b9c9-0778086ae758' User entered 'None (0)'	System	21 Sep 2020 23:27:50
	System	21 Sep 2020 23:27:50

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-21T19:27:43', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '83df83ae-c50b-48e2-b9c9-0778086ae758' User entered 'None (0)'	System	21 Sep 2020 23:27:50
	System	21 Sep 2020 23:27:50

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-21T19:27:44', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '83df83ae-c50b-48e2-b9c9-0778086ae758' User entered 'No (N)'	System	21 Sep 2020 23:27:50
	System	21 Sep 2020 23:27:50

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-21T19:27:47', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '83df83ae-c50b-48e2-b9c9-0778086ae758' User entered '21 Sep 2020 19:27'	System	21 Sep 2020 23:27:50
	System	21 Sep 2020 23:27:50

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	16 Sep 2020 12:20:02
User entered 'Day 7'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-22T19:12:45', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '157176c8-6db8-4543-939c-edea5d6fa9b0' User entered 'None (0)'	System	22 Sep 2020 23:13:05
	System	22 Sep 2020 23:13:05

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-22T19:12:46', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '157176c8-6db8-4543-939c-edea5d6fa9b0' User entered 'None (0)'	System	22 Sep 2020 23:13:05
	System	22 Sep 2020 23:13:05

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-22T19:12:48', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '157176c8-6db8-4543-939c-edea5d6fa9b0' User entered 'None (0)'	System	22 Sep 2020 23:13:05
	System	22 Sep 2020 23:13:05

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-22T19:12:51', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '157176c8-6db8-4543-939c-edea5d6fa9b0' User entered 'None (0)'	System	22 Sep 2020 23:13:05
	System	22 Sep 2020 23:13:05

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-22T19:12:53', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '157176c8-6db8-4543-939c-edea5d6fa9b0' User entered 'None (0)'	System	22 Sep 2020 23:13:05
	System	22 Sep 2020 23:13:05

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-22T19:12:55', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '157176c8-6db8-4543-939c-edea5d6fa9b0' User entered 'None (0)'	System	22 Sep 2020 23:13:05
	System	22 Sep 2020 23:13:05

US3302310

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-22T19:12:57', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '157176c8-6db8-4543-939c-edea5d6fa9b0' User entered 'No (N)'	System	22 Sep 2020 23:13:05
	System	22 Sep 2020 23:13:05

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-09-22T19:13:02', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '157176c8-6db8-4543-939c-edea5d6fa9b0' User entered '22 Sep 2020 19:13'	System	22 Sep 2020 23:13:05
	System	22 Sep 2020 23:13:05

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:22:52**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 12:20:02

**US3302310**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	23 Sep 2020 12:18:55

**US3302310**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '23 Sep 2020'	(b) (4) Wendy Taylor (b) (4)	23 Sep 2020 12:18:55

**US3302310**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Contact Made (CONTACT MADE)'	Wendy Taylor (b) (4)	23 Sep 2020 12:18:55

**US3302310**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) Wendy Taylor (b) (4)	23 Sep 2020 12:18:55

**US3302310**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	23 Sep 2020 12:18:58

**US3302310**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'I'	System	23 Sep 2020 12:18:58

**US3302310**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	30 Sep 2020 20:28:27

**US3302310**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '30 Sep 2020'	(b) (4) Brittany Belcher (b) (4)	30 Sep 2020 20:28:27

**US3302310**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Brittany Belcher (b) (4)	30 Sep 2020 20:28:27

US3302310

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) Brittany Belcher (b) (4)	30 Sep 2020 20:28:27

US3302310

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	30 Sep 2020 20:28:33

**US3302310**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'I'	System	30 Sep 2020 20:28:33

**US3302310**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 16:44:23

**US3302310**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 16:44:23

**US3302310**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Oct 2020 16:44:23

**US3302310**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 16:44:23

**US3302310**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 16:44:26

**US3302310**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'I'	System	08 Oct 2020 16:44:26

**US3302310**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	14 Oct 2020 15:26:45

US3302310

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '14 Oct 2020'	(b) (4) Brittany Belcher (b) (4)	14 Oct 2020 15:26:45

**US3302310**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Clinic (Clinic)'	(b) (4) Brittany Belcher (b) (4)	14 Oct 2020 15:26:45

**US3302310**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'VISIT3'	System	14 Oct 2020 15:26:45

**US3302310**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	14 Oct 2020 15:27:07

**US3302310**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '14 Oct 2020'	(b) (4)	14 Oct 2020 15:27:07

**US3302310**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '07:41'	(b) (4) Brittany Belcher (b) (4)	14 Oct 2020 15:27:07

**US3302310**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered '14 Oct 2020 07:41'	System	14 Oct 2020 15:27:07

US3302310

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '97.5' F	(b) (4) Brittany Belcher (b) (4)	14 Oct 2020 15:27:07

**US3302310**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Oral (Oral)'	(b) (4)	14 Oct 2020 15:27:07

**US3302310**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4)	14 Oct 2020 15:27:07

**US3302310**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '61'	(b) (4) Brittany Belcher (b) (4)	14 Oct 2020 15:27:07

**US3302310**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'bpm'	System	14 Oct 2020 15:27:07

US3302310

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '14'	(b) (4) Brittany Belcher (b) (4)	14 Oct 2020 15:27:07

**US3302310**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'breaths/min'	System	14 Oct 2020 15:27:07

**US3302310**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '113'	(b) (4) Brittany Belcher (b) (4)	14 Oct 2020 15:27:07

**US3302310**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'mmHg'	System	14 Oct 2020 15:27:07

US3302310

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '73'	(b) (4) Brittany Belcher (b) (4)	14 Oct 2020 15:27:07

**US3302310**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'mmHg'	System	14 Oct 2020 15:27:07

**US3302310**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29

**US3302310**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29

US3302310

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:22:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	14 Oct 2020 15:27:13

US3302310

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:22:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '14 Oct 2020'	(b) (4)	14 Oct 2020 15:27:13

**US3302310**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	14 Oct 2020 15:27:22

US3302310

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '14 Oct 2020'	(b) (4)	14 Oct 2020 15:27:22

US3302310

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '07:45'	(b) (4) Brittany Belcher (b) (4)	14 Oct 2020 15:27:22

**US3302310**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered '14 Oct 2020 07:45'	System	14 Oct 2020 15:27:22

US3302310

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	14 Oct 2020 15:27:26

**US3302310**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered '1'	System	14 Oct 2020 15:27:26

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 64'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-10-20T06:04:51', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '7a05f8ba-3964-4401-a87a-e907598fe479' User entered 'No (N)'	System	20 Oct 2020 10:05:11
	System	20 Oct 2020 10:05:11

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-10-20T06:05:02', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '7a05f8ba-3964-4401-a87a-e907598fe479'	System	20 Oct 2020 10:05:11
User entered 'No (N)'	System	20 Oct 2020 10:05:11

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-10-20T06:05:08', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '7a05f8ba-3964-4401-a87a-e907598fe479' User entered '20 Oct 2020 06:05:08'	System	20 Oct 2020 10:05:11
	System	20 Oct 2020 10:05:11

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 71'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-10-27T13:53:57', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'c6c14098-97ec-4cb5-a294-d1d5e07cb739' User entered 'No (N)'	System	27 Oct 2020 17:54:57
	System	27 Oct 2020 17:54:57

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-10-27T13:54:06', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'c6c14098-97ec-4cb5-a294-d1d5e07cb739'	System	27 Oct 2020 17:54:57
User entered 'Yes (Y)'	System	27 Oct 2020 17:54:57

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-10-27T13:54:17', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'c6c14098-97ec-4cb5-a294-d1d5e07cb739'	System	27 Oct 2020 17:54:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Oct 2020 17:54:57

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-10-27T13:54:46', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'c6c14098-97ec-4cb5-a294-d1d5e07cb739' User entered '27 Oct 2020 13:54:46'	System	27 Oct 2020 17:54:57
	System	27 Oct 2020 17:54:57

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 78'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-11-03T07:23:09', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'ae0e4d64-c446-47f5-9460-2c4349d47a44' User entered 'No (N)'	System	03 Nov 2020 12:23:22
	System	03 Nov 2020 12:23:22

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-11-03T07:23:14', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'ae0e4d64-c446-47f5-9460-2c4349d47a44'	System	03 Nov 2020 12:23:22
User entered 'No (N)'	System	03 Nov 2020 12:23:22

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-11-03T07:23:18', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'ae0e4d64-c446-47f5-9460-2c4349d47a44' User entered '03 Nov 2020 07:23:18'	System	03 Nov 2020 12:23:22
	System	03 Nov 2020 12:23:22

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered 'Day 92'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-11-17T06:15:33', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'b13ae5b6-7802-4ab7-aac2-b32e42466ec4' User entered 'No (N)'	System	17 Nov 2020 11:15:45
	System	17 Nov 2020 11:15:45

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-11-17T06:15:36', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'b13ae5b6-7802-4ab7-aac2-b32e42466ec4' User entered 'No (N)'	System	17 Nov 2020 11:15:45
	System	17 Nov 2020 11:15:45

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-11-17T06:15:42', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'b13ae5b6-7802-4ab7-aac2-b32e42466ec4' User entered '17 Nov 2020 06:15:42'	System	17 Nov 2020 11:15:45
	System	17 Nov 2020 11:15:45

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:19:03
Data entry locked.	System	20 Aug 2020 20:28:52
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 20:28:52

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-11-23T15:16:54', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'fb77ade5-16ea-4869-a713-ba53a9f9d732'	System	23 Nov 2020 20:17:04
User entered 'No (N)'	System	23 Nov 2020 20:17:04

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-11-23T15:16:57', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'fb77ade5-16ea-4869-a713-ba53a9f9d732'	System	23 Nov 2020 20:17:04
User entered 'No (N)'	System	23 Nov 2020 20:17:04

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-11-23T15:16:59', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'fb77ade5-16ea-4869-a713-ba53a9f9d732'	System	23 Nov 2020 20:17:04
User entered '23 Nov 2020 15:16:59'	System	23 Nov 2020 20:17:04

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-11-28T08:00:15', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'e8daf18b-8df7-4604-ba11-37c789d8bdd4'	System	28 Nov 2020 13:00:25
User entered 'No (N)'	System	28 Nov 2020 13:00:25

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-11-28T08:00:19', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'e8daf18b-8df7-4604-ba11-37c789d8bdd4' User entered 'No (N)'	System	28 Nov 2020 13:00:25
	System	28 Nov 2020 13:00:25

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-11-28T08:00:23', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'e8daf18b-8df7-4604-ba11-37c789d8bdd4' User entered '28 Nov 2020 08:00:23'	System	28 Nov 2020 13:00:25
	System	28 Nov 2020 13:00:25

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-12-05T07:23:33', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '4bd2e595-57ba-4863-aa7d-4a86a0bce6b7'	System	05 Dec 2020 12:23:42
User entered 'No (N)'	System	05 Dec 2020 12:23:42

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-12-05T07:23:36', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '4bd2e595-57ba-4863-aa7d-4a86a0bce6b7'	System	05 Dec 2020 12:23:42
User entered 'No (N)'	System	05 Dec 2020 12:23:42

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-12-05T07:23:40', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '4bd2e595-57ba-4863-aa7d-4a86a0bce6b7' User entered '05 Dec 2020 07:23:40'	System	05 Dec 2020 12:23:42
	System	05 Dec 2020 12:23:42

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-12-12T07:45:21', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '326ccb70-8199-4312-a4df-579fb23f056d' User entered 'No (N)'	System	12 Dec 2020 12:45:33
	System	12 Dec 2020 12:45:33

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-12-12T07:45:27', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '326ccb70-8199-4312-a4df-579fb23f056d' User entered 'No (N)'	System	12 Dec 2020 12:45:33
	System	12 Dec 2020 12:45:33

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-12-12T07:45:31', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '326ccb70-8199-4312-a4df-579fb23f056d' User entered '12 Dec 2020 07:45:31'	System	12 Dec 2020 12:45:33
	System	12 Dec 2020 12:45:33

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-12-19T07:59:32', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'eb66de43-7ce7-42bd-8de7-9c338ad86113'	System	19 Dec 2020 12:59:44
User entered 'No (N)'	System	19 Dec 2020 12:59:44

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-12-19T07:59:37', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'eb66de43-7ce7-42bd-8de7-9c338ad86113'	System	19 Dec 2020 12:59:44
User entered 'No (N)'	System	19 Dec 2020 12:59:44

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-12-19T07:59:41', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'eb66de43-7ce7-42bd-8de7-9c338ad86113' User entered '19 Dec 2020 07:59:41'	System	19 Dec 2020 12:59:44
	System	19 Dec 2020 12:59:44

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-12-26T08:42:15', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'eada8871-f9ea-4bbd-978b-a44c8381a4a9' User entered 'No (N)'	System	26 Dec 2020 13:42:29
	System	26 Dec 2020 13:42:29

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-12-26T08:42:20', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'eada8871-f9ea-4bbd-978b-a44c8381a4a9' User entered 'No (N)'	System	26 Dec 2020 13:42:29
	System	26 Dec 2020 13:42:29

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2020-12-26T08:42:24', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'eada8871-f9ea-4bbd-978b-a44c8381a4a9' User entered '26 Dec 2020 08:42:24'	System	26 Dec 2020 13:42:29
	System	26 Dec 2020 13:42:29

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2021-01-02T09:17:42', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '68961a8c-df3d-4802-bab9-1d263adc89f6'	System	02 Jan 2021 14:17:52
User entered 'No (N)'	System	02 Jan 2021 14:17:52

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2021-01-02T09:17:44', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '68961a8c-df3d-4802-bab9-1d263adc89f6'	System	02 Jan 2021 14:17:52
User entered 'No (N)'	System	02 Jan 2021 14:17:52

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2021-01-02T09:17:50', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '68961a8c-df3d-4802-bab9-1d263adc89f6' User entered '02 Jan 2021 09:17:50'	System	02 Jan 2021 14:17:52
	System	02 Jan 2021 14:17:52

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2021-01-09T08:53:08', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6cdb218b-bf6d-4b15-ab50-53fa57d93fda' User entered 'No (N)'	System	09 Jan 2021 13:53:20
	System	09 Jan 2021 13:53:20

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2021-01-09T08:53:11', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6cdb218b-bf6d-4b15-ab50-53fa57d93fda' User entered 'No (N)'	System	09 Jan 2021 13:53:20
	System	09 Jan 2021 13:53:20

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2021-01-09T08:53:15', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6cdb218b-bf6d-4b15-ab50-53fa57d93fda' User entered '09 Jan 2021 08:53:15'	System	09 Jan 2021 13:53:20
	System	09 Jan 2021 13:53:20

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2021-01-16T04:58:50', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '93cc3db0-1267-4db9-890d-abbae2e11a4d' User entered 'No (N)'	System	16 Jan 2021 09:58:59
	System	16 Jan 2021 09:58:59

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2021-01-16T04:58:52', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '93cc3db0-1267-4db9-890d-abbae2e11a4d' User entered 'No (N)'	System	16 Jan 2021 09:58:59
	System	16 Jan 2021 09:58:59

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A1512E38-CA97-45F0-9F7C-C4FE947AD017)', Time: '2021-01-16T04:58:56', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '93cc3db0-1267-4db9-890d-abbae2e11a4d' User entered '16 Jan 2021 04:58:56'	System	16 Jan 2021 09:58:59
	System	16 Jan 2021 09:58:59

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-01-25T09:57:46', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'a6562a55-b69e-481d-b267-f3ffd1f78850' User entered 'No (N)'	System	25 Jan 2021 14:58:25

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-01-25T09:57:47', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'a6562a55-b69e-481d-b267-f3ffd1f78850'	System	25 Jan 2021 14:58:25
User entered 'No (N)'	System	25 Jan 2021 14:58:25

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-01-25T09:57:53', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'a6562a55-b69e-481d-b267-f3ffd1f78850' User entered '25 Jan 2021 09:57:53'	System	25 Jan 2021 14:58:25
	System	25 Jan 2021 14:58:25

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-01-30T07:39:46', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'f20d62df-cc21-48fe-9fff-d50c9d6d063c'	System	30 Jan 2021 12:39:58
User entered 'No (N)'	System	30 Jan 2021 12:39:58

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-01-30T07:39:48', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'f20d62df-cc21-48fe-9fff-d50c9d6d063c'	System	30 Jan 2021 12:39:58
User entered 'No (N)'	System	30 Jan 2021 12:39:58

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-01-30T07:39:52', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'f20d62df-cc21-48fe-9fff-d50c9d6d063c' User entered '30 Jan 2021 07:39:52'	System	30 Jan 2021 12:39:58
	System	30 Jan 2021 12:39:58

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-02-06T08:16:47', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '40c0c248-e6ea-4044-a47d-4dd13f3f2917'	System	06 Feb 2021 13:16:57
User entered 'No (N)'	System	06 Feb 2021 13:16:57

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-02-06T08:16:49', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '40c0c248-e6ea-4044-a47d-4dd13f3f2917'	System	06 Feb 2021 13:16:57
User entered 'No (N)'	System	06 Feb 2021 13:16:57

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-02-06T08:16:52', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '40c0c248-e6ea-4044-a47d-4dd13f3f2917'	System	06 Feb 2021 13:16:57
User entered '06 Feb 2021 08:16:52'	System	06 Feb 2021 13:16:57

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-02-13T08:17:23', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '3feea998-5d61-4301-abb7-d0bcb3410b27' User entered 'No (N)'	System	13 Feb 2021 13:17:32
	System	13 Feb 2021 13:17:32

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-02-13T08:17:26', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '3feea998-5d61-4301-abb7-d0bcb3410b27'	System	13 Feb 2021 13:17:32
User entered 'No (N)'	System	13 Feb 2021 13:17:32

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-02-13T08:17:30', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '3feea998-5d61-4301-abb7-d0bcb3410b27' User entered '13 Feb 2021 08:17:30'	System	13 Feb 2021 13:17:32
	System	13 Feb 2021 13:17:32

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-02-20T07:16:47', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6c59dab8-d63d-449e-888f-e54fd24c766f' User entered 'No (N)'	System	20 Feb 2021 12:16:55
	System	20 Feb 2021 12:16:55

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-02-20T07:16:49', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6c59dab8-d63d-449e-888f-e54fd24c766f' User entered 'No (N)'	System	20 Feb 2021 12:16:55

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-02-20T07:16:53', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '6c59dab8-d63d-449e-888f-e54fd24c766f' User entered '20 Feb 2021 07:16:53'	System	20 Feb 2021 12:16:55
	System	20 Feb 2021 12:16:55

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-02-27T06:03:08-05:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '92c31f61-4e2a-43fc-b826-30b8e28ab5ea' User entered 'No (N)'	System	27 Feb 2021 11:03:17
	System	27 Feb 2021 11:03:17

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-02-27T06:03:10-05:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '92c31f61-4e2a-43fc-b826-30b8e28ab5ea' User entered 'No (N)'	System	27 Feb 2021 11:03:17
	System	27 Feb 2021 11:03:17

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-02-27T06:03:13-05:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '92c31f61-4e2a-43fc-b826-30b8e28ab5ea' User entered '27 Feb 2021 11:03:13'	System	27 Feb 2021 11:03:17
	System	27 Feb 2021 11:03:17

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-03-06T07:28:55-05:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'ef62b005-32d6-4926-b6d8-22b6b3e68cfc'	System	06 Mar 2021 12:29:08
User entered 'No (N)'	System	06 Mar 2021 12:29:08

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-03-06T07:28:57-05:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'ef62b005-32d6-4926-b6d8-22b6b3e68cfc'	System	06 Mar 2021 12:29:08
User entered 'No (N)'	System	06 Mar 2021 12:29:08

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-03-06T07:29:03-05:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'ef62b005-32d6-4926-b6d8-22b6b3e68cfc' User entered '06 Mar 2021 07:29:03'	System	06 Mar 2021 12:29:08
	System	06 Mar 2021 12:29:08

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-03-13T05:57:51-05:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '7091a148-c34f-480f-a09d-335ae79d8190'	System	13 Mar 2021 10:58:37
User entered 'Yes (Y)'	System	13 Mar 2021 10:58:37

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-03-13T05:57:54-05:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '7091a148-c34f-480f-a09d-335ae79d8190'	System	13 Mar 2021 10:58:37
User entered 'No (N)'	System	13 Mar 2021 10:58:37

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-03-13T05:58:00-05:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '7091a148-c34f-480f-a09d-335ae79d8190'	System	13 Mar 2021 10:58:37
User entered 'No (N)'	System	13 Mar 2021 10:58:37

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-03-13T05:58:10-05:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '7091a148-c34f-480f-a09d-335ae79d8190'	System	13 Mar 2021 10:58:37
User entered 'Yes (Y)'	System	13 Mar 2021 10:58:37

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-03-13T05:58:17-05:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '7091a148-c34f-480f-a09d-335ae79d8190'	System	13 Mar 2021 10:58:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Mar 2021 10:58:37

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-03-13T05:58:28-05:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '7091a148-c34f-480f-a09d-335ae79d8190'	System	13 Mar 2021 10:58:37
User entered '13 Mar 2021 05:58:28'	System	13 Mar 2021 10:58:37

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-03-20T07:52:37-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'f0c469ba-5eb1-4a67-9b3e-e4a26c49c335'	System	20 Mar 2021 11:52:47
User entered 'No (N)'	System	20 Mar 2021 11:52:47

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-03-20T07:52:41-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'f0c469ba-5eb1-4a67-9b3e-e4a26c49c335'	System	20 Mar 2021 11:52:47
User entered 'No (N)'	System	20 Mar 2021 11:52:47

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-03-20T07:52:44-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'f0c469ba-5eb1-4a67-9b3e-e4a26c49c335' User entered '20 Mar 2021 07:52:44'	System	20 Mar 2021 11:52:47
	System	20 Mar 2021 11:52:47

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-03-27T08:29:10-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'b35d9670-64fc-44d5-9399-eb4859fd11f7'	System	27 Mar 2021 12:29:20
User entered 'No (N)'	System	27 Mar 2021 12:29:20

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-03-27T08:29:12-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'b35d9670-64fc-44d5-9399-eb4859fd11f7'	System	27 Mar 2021 12:29:20
User entered 'No (N)'	System	27 Mar 2021 12:29:20

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-03-27T08:29:16-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'b35d9670-64fc-44d5-9399-eb4859fd11f7'	System	27 Mar 2021 12:29:20
User entered '27 Mar 2021 08:29:16'	System	27 Mar 2021 12:29:20

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-04-03T07:59:59-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'd45a52ed-2543-40d8-8498-64f0e5957bc3'	System	03 Apr 2021 12:00:09
User entered 'No (N)'	System	03 Apr 2021 12:00:09

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-04-03T08:00:02-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'd45a52ed-2543-40d8-8498-64f0e5957bc3'	System	03 Apr 2021 12:00:09
User entered 'No (N)'	System	03 Apr 2021 12:00:09

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-04-03T08:00:05-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'd45a52ed-2543-40d8-8498-64f0e5957bc3'	System	03 Apr 2021 12:00:09
User entered '03 Apr 2021 08:00:05'	System	03 Apr 2021 12:00:09

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-04-10T08:53:20-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '747f24b0-cc1e-48f2-ae42-8333e43414ae' User entered 'No (N)'	System	10 Apr 2021 12:53:41
	System	10 Apr 2021 12:53:41

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-04-10T08:53:22-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '747f24b0-cc1e-48f2-ae42-8333e43414ae' User entered 'No (N)'	System	10 Apr 2021 12:53:41

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-04-10T08:53:25-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '747f24b0-cc1e-48f2-ae42-8333e43414ae' User entered '10 Apr 2021 08:53:25'	System	10 Apr 2021 12:53:41
	System	10 Apr 2021 12:53:41

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-04-17T07:34:55-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '06b848a8-1fa3-44b7-a8d6-7578ad2c0fe2'	System	17 Apr 2021 11:35:11
User entered 'No (N)'	System	17 Apr 2021 11:35:11

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-04-17T07:34:58-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '06b848a8-1fa3-44b7-a8d6-7578ad2c0fe2'	System	17 Apr 2021 11:35:11
User entered 'No (N)'	System	17 Apr 2021 11:35:11

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-04-17T07:35:05-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '06b848a8-1fa3-44b7-a8d6-7578ad2c0fe2'	System	17 Apr 2021 11:35:11
User entered '17 Apr 2021 07:35:05'	System	17 Apr 2021 11:35:11

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-04-24T08:52:53-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '005c5173-8615-4027-ad7d-3b29775a89a2'	System	24 Apr 2021 12:53:00
User entered 'No (N)'	System	24 Apr 2021 12:53:00

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-04-24T08:52:55-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '005c5173-8615-4027-ad7d-3b29775a89a2'	System	24 Apr 2021 12:53:00
User entered 'No (N)'	System	24 Apr 2021 12:53:00

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-04-24T08:52:58-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: '005c5173-8615-4027-ad7d-3b29775a89a2'	System	24 Apr 2021 12:53:00
User entered '24 Apr 2021 08:52:58'	System	24 Apr 2021 12:53:00

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-05-01T08:08:12-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'fd35f276-630f-4ee6-9e9c-0a80d537b875'	System	01 May 2021 12:08:38
User entered 'No (N)'	System	01 May 2021 12:08:38

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-05-01T08:08:14-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'fd35f276-630f-4ee6-9e9c-0a80d537b875'	System	01 May 2021 12:08:38
User entered 'No (N)'	System	01 May 2021 12:08:38

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-05-01T08:08:19-04:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'fd35f276-630f-4ee6-9e9c-0a80d537b875'	System	01 May 2021 12:08:38
User entered '01 May 2021 08:08:19'	System	01 May 2021 12:08:38

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 00:11:16

**US3302310**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:16
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 00:11:16

US3302310

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:22:52

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:35:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-03-06T07:29:10-05:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'a39ab523-fa16-4bee-ab11-e216e6acc9d7'	System	06 Mar 2021 12:29:21
User entered 'No (N)'	System	06 Mar 2021 12:29:21

**US3302310**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:35:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BEC14910-7A88-430D-AE61-E1D35B1B0F6E)', Time: '2021-03-06T07:29:17-05:00', User OID: 'PatientReportedOutcome (US3302310)', ODM File OID: 'a39ab523-fa16-4bee-ab11-e216e6acc9d7'	System	06 Mar 2021 12:29:21
User entered '06 Mar 2021 07:29:17'	System	06 Mar 2021 12:29:21

**US3302310**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:30:32

**US3302310**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 20:30:32

**US3302310**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Nov 2020 20:30:32

**US3302310**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 20:30:32

**US3302310**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 20:30:35

**US3302310**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:14:29
User entered 'I'	System	11 Nov 2020 20:30:35

**US3302310**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 16:42:46

**US3302310**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '15 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 16:42:46

**US3302310**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Dec 2020 16:42:46

**US3302310**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 16:42:46

**US3302310**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 16:42:50

**US3302310**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User entered '1'	System	15 Dec 2020 16:42:50

**US3302310**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 15:09:04

**US3302310**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '14 Jan 2021'	(b) (4), (b) (6)	14 Jan 2021 15:09:04

**US3302310**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Jan 2021 15:09:04

**US3302310**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 15:09:04

**US3302310**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 15:09:11

**US3302310**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User entered 'I'	System	14 Jan 2021 15:09:11

**US3302310**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	10 Feb 2021 19:31:54

**US3302310**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '10 Feb 2021'	(b) (4) Wendy Taylor (b) (4)	10 Feb 2021 19:31:54

**US3302310**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	10 Feb 2021 19:31:54

**US3302310**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) Wendy Taylor (b) (4)	10 Feb 2021 19:31:54

**US3302310**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	10 Feb 2021 19:32:00

**US3302310**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User entered 'I'	System	10 Feb 2021 19:32:00

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:18:54

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:18:54

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:18:54

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User entered 'VISIT4'	System	24 Mar 2021 20:18:54

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:00:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:31:02

US3302310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:00:44
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:31:02

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:00:44
User entered '15:54'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:31:02

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User entered '23 Mar 2021 15:54'	System	01 Apr 2021 18:31:02

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:00:44
User entered '98.4' F	(b) (4), (b) (6)	01 Apr 2021 18:31:02

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:00:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:31:02

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:00:44
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:31:02

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:00:44
User entered '69'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:31:02

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User entered 'bpm'	System	01 Apr 2021 18:31:02

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:00:44
User entered '18'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:31:02

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User entered 'breaths/min'	System	01 Apr 2021 18:31:02

US3302310

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:00:44
User entered '123'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:31:02

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User entered 'mmHg'	System	01 Apr 2021 18:31:02

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:00:44
User entered '80'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:31:02

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User entered 'mmHg'	System	01 Apr 2021 18:31:02

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:22:52**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:18:58

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:22:52**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:18:58

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:19:07

US3302310

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:52

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:19:07

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered '15:56'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:19:07

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User entered '23 Mar 2021 15:56'	System	24 Mar 2021 20:19:07

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:19:12

**US3302310**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:19:03
User entered '1'	System	24 Mar 2021 20:19:12

**US3302310**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:33:42
	(b) (4)	
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	12 Apr 2021 15:17:35

**US3302310**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:33:42
	(b) (4)	
User entered '12 Apr 2021'	Wendy Taylor (b) (4)	12 Apr 2021 15:17:35

**US3302310**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:33:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	12 Apr 2021 15:17:35

**US3302310**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:33:42
User entered empty.	(b) (4)	
	Wendy Taylor (b) (4)	12 Apr 2021 15:17:35

US3302310

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:33:42
	(b) (4)	
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	12 Apr 2021 15:17:41

**US3302310**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 15:17:41

US3302310

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:22:52

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:09:44
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User closed query 'Sorry, it was the swab that was taken by Luxor Scientific on 30Oct2020, not 30Dec2020.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 22:42:28
Query 'Sorry, it was the swab that was taken by Luxor Scientific on 30Oct2020, not 30Dec2020.' answered with 'this has been added to covid diagnostic test eCRF. please confirm if now correct' (Site from CRA).	brittany cooksey (b) (4) (b) (4)	27 Jan 2021 21:34:23
User opened query 'Sorry, it was the swab that was taken by Luxor Scientific on 30Oct2020, not 30Dec2020.' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 21:54:31
User closed query 'Per eCRF Guidelines, please complete page. It should not have been deactivated. Since original Day 1 swab was negative, but swab on 30Dec2020 was positive, two Covid folders are to be completed.' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 21:54:31
User entered '23 Nov 2020' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	13 Jan 2021 18:45:54
Query 'Per eCRF Guidelines, please complete page. It should not have been deactivated. Since original Day 1 swab was negative, but swab on 30Dec2020 was positive, two Covid folders are to be completed.' answered with 'sorry im not seeing where this subject had a visit on 30DEC2020' (Site from CRA).	brittany cooksey (b) (4) (b) (4)	08 Jan 2021 19:27:53
User closed query 'Per CDM: It appears there are two Covis-19 Assessments folders with dates of 26OCT2020. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 08:18:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Jan 2021 08:18:19
User opened query 'Per eCRF Guidelines, please complete page. It should not have been deactivated. Since original Day 1 swab was negative, but swab on 30Dec2020 was positive, two Covid folders are to be completed.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 19:50:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Jan 2021 19:46:39

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US3302310

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:22:52

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 17:23:23
Query 'Data is required. Please complete.' answered with 'DUPLICATE. page entered in error' (Site from System).	brittany cooksey (b) (4)	10 Nov 2020 15:39:24
Query 'Per CDM: It appears there are two Covis-19 Assessments folders with dates of 26OCT2020. Please reconcile.' answered with 'DUPLICATE. page entered in error' (Site from DM).	brittany cooksey (b) (4)	10 Nov 2020 15:39:20
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 15:39:03
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 15:39:03
User opened query 'Per CDM: It appears there are two Covis-19 Assessments folders with dates of 26OCT2020. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 20:37:21
User entered '26 Oct 2020' reason for change: Data Entry Error	Wendy Taylor (b) (4)	06 Nov 2020 20:28:49
User entered '24 Oct 2020' reason for change: Data Entry Error	Wendy Taylor (b) (4)	06 Nov 2020 20:26:39
User entered '26 Oct 2020'	Wendy Taylor (b) (4)	06 Nov 2020 20:17:07

US3302310

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:22:52

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:09:44
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '16:10' reason for change: Data Entry Error	brittany cooksey (b) (4)	13 Jan 2021 18:45:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Jan 2021 08:18:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Jan 2021 19:46:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 17:23:23
Query 'Data is required. Please complete.' answered with 'DUPLICATE. page entered in error' (Site from System).	brittany cooksey (b) (4)	10 Nov 2020 15:39:28
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 15:39:03
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 15:39:03
User entered '09:00'	Wendy Taylor (b) (4)	06 Nov 2020 20:17:07

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Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:22:52

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:25
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 23-NOV-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 23-NOV-2020 is missing in EDC. Kindly confirm if swab sample was collected if yes, consider updating swab data in the COVID Diagnostic Test eCRF, else clarify.' canceled (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 10:31:06
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 23-NOV-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 23-NOV-2020 is missing in EDC. Kindly confirm if swab sample was collected if yes, consider updating swab data in the COVID Diagnostic Test eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 05:41:01
User entered '23 Nov 2020 16:10'	System	13 Jan 2021 18:45:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Jan 2021 19:46:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 17:23:23
User entered empty.	System	10 Nov 2020 15:39:03
User entered '26 Oct 2020 09:00'	System	06 Nov 2020 20:28:49
User entered '24 Oct 2020 09:00'	System	06 Nov 2020 20:26:39
User entered '26 Oct 2020 09:00'	System	06 Nov 2020 20:17:07

US3302310

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:22:52

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:09:44
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)' reason for change: Data Entry Error	brittany cooksey (b) (4)	13 Jan 2021 18:45:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Jan 2021 08:18:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Jan 2021 19:46:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 17:23:23
Query 'Data is required. Please complete.' answered with 'DUPLICATE. page entered in error' (Site from System).	brittany cooksey (b) (4)	10 Nov 2020 15:39:32
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 15:39:03
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 15:39:03
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Wendy Taylor (b) (4)	06 Nov 2020 20:17:07

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Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:22:52

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:09:44
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'No (N)' reason for change: Data Entry Error	brittany cooksey (b) (4)	13 Jan 2021 18:45:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Jan 2021 08:18:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Jan 2021 19:46:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 17:23:23
Query 'Data is required. Please complete.' answered with 'DUPLICATE. page entered in error' (Site from System).	brittany cooksey (b) (4)	10 Nov 2020 15:39:36
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 15:39:03
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 15:39:03
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	06 Nov 2020 20:17:07

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Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:52

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:26
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	13 Jan 2021 18:50:31
User entered '23 Nov 2020' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 18:50:31
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:47:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Jan 2021 19:46:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 17:23:39
User entered '26 Oct 2020'	Wendy Taylor (b) (4)	06 Nov 2020 20:18:37

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Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:52

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:37
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:47:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Jan 2021 19:46:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 17:23:39
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	06 Nov 2020 20:18:37

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Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:52

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User closed query 'Per CDM re-query: Thank you for your answer. Please consider adding this under AE form also. Thank you!' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 08:45:19
Query 'Per CDM re-query: Thank you for your answer. Please consider adding this under AE form also. Thank you!' answered with 'AE added. subject was asymptomatic so start end date is recorded as the same' (Site from DM).	brittany cooksey (b) (4)	18 Jan 2021 19:27:24
User opened query 'Per CDM re-query: Thank you for your answer. Please consider adding this under AE form also. Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 11:21:09
User closed query 'Per CDM: Thank you for your answer. However, there is no AE added with corresponding dates. Please consider adding missing Adverse Event form. Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 11:21:09
Query 'Per CDM: Thank you for your answer. However, there is no AE added with corresponding dates. Please consider adding missing Adverse Event form. Thank you!' answered with 'subject tested positive for COVID 23OCT-05NOV2020. Subject then was positive at day 28 visit. Should this be another entry of COVID on AE log' (Site from DM).	brittany cooksey (b) (4)	15 Jan 2021 15:20:20
User opened query 'Per CDM: Thank you for your answer. However, there is no AE added with corresponding dates. Please consider adding missing Adverse Event form. Thank you!' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 10:37:02
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	15 Jan 2021 10:36:28
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'AE added' (Site from System).	brittany cooksey (b) (4)	13 Jan 2021 18:50:44

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Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:52

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System). DataPoint Un-verified.	System	13 Jan 2021 18:50:31
	brittany cooksey (b) (4)	13 Jan 2021 18:50:31
User entered 'Yes (Y)' reason for change: Data Entry Error	brittany cooksey (b) (4)	13 Jan 2021 18:50:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 19:47:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Jan 2021 19:46:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 17:23:39
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	06 Nov 2020 20:18:54
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered by data change (Site from System).	System	06 Nov 2020 20:18:54
User entered 'No (N)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	06 Nov 2020 20:18:54
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	06 Nov 2020 20:18:37
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	06 Nov 2020 20:18:37

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Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:52

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:37
User closed query 'Per GCL Lab Reconciliation: Swab: Requery: Response noted however, corresponding unscheduled sample collected on 23-NOV-2020 details not updated in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 19:08:33
Query 'Per GCL Lab Reconciliation: Swab: Requery: Brittany Belcher Response noted however, corresponding unscheduled sample collected on 23-NOV-2020 details not updated in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' answered with 'Confirmed Data entered is correct. Lab report has been received for this and uploaded in source. Requisition ID: 1F604753639 and Lab Report Accession: 1F609GU' (Site from DM).	(b) (4)	29 Apr 2021 13:12:42
User opened query 'Per GCL Lab Reconciliation: Swab: Requery: Response noted however, corresponding unscheduled sample collected on 23-NOV-2020 details not updated in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 06:31:28
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 23-NOV-2020 is recorded under Covid-19 Assessment in EDC & in Preclarus is present as Unscheduled visit with accession number # 1F650734215 & # 1F633973255 and requisition kit ID # 1F604753639. Kindly review and confirm in site response, if swab sample collected on 23-NOV-2020 was to analyse illness visit or COVID symptoms if yes, confirm in site response the correct visit name to be updated in Preclarus, else confirm, if it was an additional swab sample or if collected in error.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 06:31:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:30

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Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:52

Date of Test

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 23-NOV-2020 is recorded under Covid-19 Assessment in EDC & in Preclarus is present as Unscheduled visit with accession number # 1F650734215 & # 1F633973255 and requisition kit ID # 1F604753639. Kindly review and confirm in site response, if swab sample collected on 23-NOV-2020 was to analyse illness visit or COVID symptoms if yes, confirm in site response the correct visit name to be updated in Preclarus, else confirm, if it was an additional swab sample or if collected in error.' answered with 'Per source, the data entered is correct. ' (Site from DM).	Brittany Belcher (b) (4)	07 Apr 2021 12:27:20
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 23-NOV-2020 is recorded under Covid-19 Assessment in EDC & in Preclarus is present as Unscheduled visit with accession number # 1F650734215 & # 1F633973255 and requisition kit ID # 1F604753639. Kindly review and confirm in site response, if swab sample collected on 23-NOV-2020 was to analyse illness visit or COVID symptoms if yes, confirm in site response the correct visit name to be updated in Preclarus, else confirm, if it was an additional swab sample or if collected in error.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 10:31:49
User closed query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 09:00:45
Query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' answered with 'Data has been entered. ' (Site from DM).	Brittany Belcher (b) (4)	17 Mar 2021 17:22:02

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Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:52

[Date of Test](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 17:17:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Un-verified.	(b) (4)	
	brittany cooksey (b) (4)	13 Jan 2021 18:50:31
	(b) (4)	
User entered '23 Nov 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	13 Jan 2021 18:50:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:47:01
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Jan 2021 19:46:51
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 17:23:39
	(b) (4), (b) (6)	
User entered '26 Oct 2020'	Wendy Taylor (b) (4)	06 Nov 2020 20:18:37
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:52

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:37
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:47:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Jan 2021 19:46:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 17:23:39
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Wendy Taylor (b) (4)	06 Nov 2020 20:18:37

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Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:52

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:37
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:47:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Jan 2021 19:46:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 17:23:39
User entered empty.	Wendy Taylor (b) (4)	06 Nov 2020 20:18:37

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Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:52

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:37
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:47:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Jan 2021 19:46:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 17:23:39
User entered 'No (N)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	06 Nov 2020 20:19:03
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	06 Nov 2020 20:18:37

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Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:52

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:37
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:47:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Jan 2021 19:46:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 17:23:39
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Nov 2020 20:19:03
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Nov 2020 20:18:37
User entered empty.	Wendy Taylor (b) (4)	06 Nov 2020 20:18:37

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Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:52

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:37
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:47:01
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Jan 2021 19:46:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 17:23:39
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Nov 2020 20:19:03
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Nov 2020 20:18:37
User entered empty.	Wendy Taylor (b) (4)	06 Nov 2020 20:18:37

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Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:52

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:37
User entered '1'	System	13 Jan 2021 18:50:31
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	07 Jan 2021 19:46:51
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 17:23:39
User entered '0'	System	06 Nov 2020 20:18:54
User entered '1'	System	06 Nov 2020 20:18:37

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:52

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:18:22

**US3302310**

**Folder: Covid-19 Assessment 23 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:18:22

**US3302310**

**Folder: Covid-19 Assessment 23 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:18:22

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:52

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:18:22

**US3302310**

**Folder: Covid-19 Assessment 23 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

[Did the subject have Heart Rate  \$\geq\$  125 beats per minute](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:18:22

**US3302310**

**Folder: Covid-19 Assessment 23 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:18:22

**US3302310**

**Folder: Covid-19 Assessment 23 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:18:22

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:52

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:18:22

**US3302310**

**Folder: Covid-19 Assessment 23 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

[Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:08
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:18:22

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[Start Date](#)

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[Oxygen Saturation](#)

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:08
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[PaO2](#)

Audit	User	Time (GMT)
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[Did the subject have Respiratory failure?](#)

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

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Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:57
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[High-Flow Oxygen?](#)

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DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:08
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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:08
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[Mechanical Ventilation?](#)

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[ECMO?](#)

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

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[Evidence of Shock Requires  
Vasopressors](#)

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[Acute Renal Dysfunction?](#)

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[Hepatic Dysfunction?](#)

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[Neurologic Dysfunction?](#)

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[Clinical Evidence](#)

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[Radiographical Evidence](#)

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**Folder: Covid-19 Assessment 23 Nov 2020**

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[Admission to an intensive care unit due to SARS-CoV-2](#)

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[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:37
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 23-NOV-2020 is reported under Unscheduled visit in PPD portal; however, the corresponding swab sample is missing in EDC for date 23-NOV-2020. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating swab data in the Covid Diagnostic Test eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 05:40:24
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 23-NOV-2020 is reported under Unscheduled visit in PPD portal; however, the corresponding swab sample is missing in EDC for date 23-NOV-2020. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating swab data in the Covid Diagnostic Test eCRF, else clarify.' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	13 Jan 2021 18:56:50
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 23-NOV-2020 is reported under Unscheduled visit in PPD portal; however, the corresponding swab sample is missing in EDC for date 23-NOV-2020. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating swab data in the Covid Diagnostic Test eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 06:21:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 00:45:47
User closed query 're-query: You will go to Add Event and select COVID-19 Illness Visit ' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 04:09:50
User entered '26 Oct 2020' reason for change: Data Entry Error	Wendy Taylor (b) (4)	06 Nov 2020 20:28:57

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

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[Date of Contact](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020' reason for change: Data Entry Error	Wendy Taylor (b) (4)	06 Nov 2020 20:26:58
Query 're-query: You will go to Add Event and select COVID-19 Illness Visit ' answered with 'updated' (Site from CRA).	Wendy Taylor (b) (4)	06 Nov 2020 20:20:13
User opened query 're-query: You will go to Add Event and select COVID-19 Illness Visit ' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 19:27:26
User closed query 'Please add the following missing pages: 1. Severity page 2. Illness Day 1 3. Saliva Log' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 19:27:26
Query 'Please add the following missing pages: 1. Severity page 2. Illness Day 1 3. Saliva Log' answered with 'unable to find illness day and saliva log' (Site from CRA).	brittany cooksey (b) (4)	06 Nov 2020 17:46:27
User opened query 'Please add the following missing pages: 1. Severity page 2. Illness Day 1 3. Saliva Log' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 01:22:13
User entered '26 Oct 2020'	brittany cooksey (b) (4)	26 Oct 2020 14:04:01

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:22:52

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:37
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:41:13
User closed query 'Please review source and revise if needed. Monitor could not find time of contact noted in Source as 09:00. The earliest contact time that appears in Source is 9:15 (Rest start time) for Vitals.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:41:10
Query 'Please review source and revise if needed. Monitor could not find time of contact noted in Source as 09:00. The earliest contact time that appears in Source is 9:15 (Rest start time) for Vitals.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	10 Nov 2020 15:40:22
User entered '09:15' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 15:40:14
User opened query 'Please review source and revise if needed. Monitor could not find time of contact noted in Source as 09:00. The earliest contact time that appears in Source is 9:15 (Rest start time) for Vitals.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 00:51:31
User entered '09:00'	brittany cooksey (b) (4)	26 Oct 2020 14:04:01

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:22:52**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:37
User entered '26 Oct 2020 09:15'	System	10 Nov 2020 15:40:14
User entered '26 Oct 2020 09:00'	System	06 Nov 2020 20:28:57
User entered '24 Oct 2020 09:00'	System	06 Nov 2020 20:26:58
User entered '26 Oct 2020 09:00'	System	26 Oct 2020 14:04:01

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:22:52**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:37
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 00:48:20
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	brittany cooksey (b) (4)	26 Oct 2020 14:04:01

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:22:52**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:37
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 00:45:56
User entered 'Yes (Y)'	brittany cooksey (b) (4)	26 Oct 2020 14:04:01

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Day 1 (Day 1)'	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:52

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User closed query 'Per CDM; Please confirm that initial date of symptoms and Contact date are the same (26OCT2020) or update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:21:56
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:53:22
User closed query 'Day 1 of the symptom Log is supposed to be the first day the subject is reporting the symptoms. Please review source and revise if needed. Progress notes states that subject left a VM on 23Oct2020 evening stating that she was experiencing muscle aches. In addition, in the progress notes, it states that subject contacted the site on 24Oct2020 and stated that she was experiencing a sore throat and muscle aches. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:53:15
Query 'Day 1 of the symptom Log is supposed to be the first day the subject is reporting the symptoms. Please review source and revise if needed. Progress notes states that subject left a VM on 23Oct2020 evening stating that she was experiencing muscle aches. In addition, in the progress notes, it states that subject contacted the site on 24Oct2020 and stated that she was experiencing a sore throat and muscle aches. ' answered with 'EDC updated and PN made in source for clarification on error' (Site from CRA).	brittany cooksey (b) (4) (b) (4)	10 Nov 2020 15:02:03
User entered '23 Oct 2020' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	10 Nov 2020 14:55:21
Query 'Per CDM; Please confirm that initial date of symptoms and Contact date are the same (26OCT2020) or update accordingly.' answered with 'same' (Site from DM).	brittany cooksey (b) (4) (b) (4)	10 Nov 2020 14:11:09
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 02:49:00
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:52

[Date](#)

Audit	User	Time (GMT)
User opened query 'Day 1 of the symptom Log is supposed to be the first day the subject is reporting the symptoms. Please review source and revise if needed. Progress notes states that subject left a VM on 23Oct2020 evening stating that she was experiencing muscle aches. In addition, in the progress notes, it states that subject contacted the site on 24Oct2020 and stated that she was experiencing a sore throat and muscle aches. ' (Site from CRA). User opened query 'Per CDM; Please confirm that initial date of symptoms and Contact date are the same (26OCT2020) or update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 02:04:51
User entered '26 Oct 2020'	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:33:18
User closed query 'Per CDM: "Assessment Not Done" is checked, however assessments are present. Please update. Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 09:23:58
Query 'Per CDM: "Assessment Not Done" is checked, however assessments are present. Please update. Thank you!' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	15 Jan 2021 14:28:04
User entered '0' reason for change: Data Entry Error	brittany cooksey (b) (4)	15 Jan 2021 14:27:20
User opened query 'Per CDM: "Assessment Not Done" is checked, however assessments are present. Please update. Thank you!' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 12:54:53
DataPoint Un-verified.	brittany cooksey (b) (4)	13 Jan 2021 19:05:30
User entered '1' reason for change: Data Entry Error	brittany cooksey (b) (4)	13 Jan 2021 19:05:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '0'	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:52

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:33:24
User closed query 'Per CDM: It appears that "Temperature" and "O2 Saturation" are not recorded. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 09:24:00
Query 'Per CDM: It appears that "Temperature" and "O2 Saturation" are not recorded. If not collected, please consider recording these as "Not Done". Thank you!' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	15 Jan 2021 14:28:08
DataPoint Un-verified.	brittany cooksey (b) (4)	15 Jan 2021 14:27:20
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4)	15 Jan 2021 14:27:20
User opened query 'Per CDM: It appears that "Temperature" and "O2 Saturation" are not recorded. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 12:53:08
User closed query 'Per CDM: It appears that O2 Saturation and temperature were not provided for days 1-3. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 12:53:08
Query 'Per CDM: It appears that O2 Saturation and temperature were not provided for days 1-3. If not collected, please consider recording as Not Done.' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	13 Jan 2021 19:05:45
User opened query 'Per CDM: It appears that O2 Saturation and temperature were not provided for days 1-3. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 17:06:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered empty.	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:22:52**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User entered '%'	System	15 Jan 2021 14:27:20
User entered empty.	System	26 Oct 2020 14:05:33

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Form: Symptom Log (1)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:33:26
User closed query 'Per CDM: It appears that "Temperature" is not recorded. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 08:54:08
Query 'Per CDM: It appears that "Temperature" is not recorded. If not collected, please consider recording these as "Not Done". Thank you!' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	18 Jan 2021 19:29:46
DataPoint Un-verified.	brittany cooksey (b) (4)	18 Jan 2021 19:29:31
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4)	18 Jan 2021 19:29:31
User opened query 'Per CDM: It appears that "Temperature" is not recorded. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 09:24:07
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:53:34
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '98.8' F	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:53:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:57:11
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'Mild (Mild)'	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'Mild (Mild)'	brittany cooksey (b) (4)	26 Oct 2020 14:05:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Day 2 (Day 2)'	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:53:59
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
User entered '24 Oct 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '27 Oct 2020'	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:34:12
User closed query 'Per CDM: "Assessment Not Done" is checked, however assessments are present. Please update. Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 09:24:14
Query 'Per CDM: "Assessment Not Done" is checked, however assessments are present. Please update. Thank you!' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	15 Jan 2021 14:28:15
User entered '0' reason for change: Data Entry Error	brittany cooksey (b) (4)	15 Jan 2021 14:27:20
User opened query 'Per CDM: "Assessment Not Done" is checked, however assessments are present. Please update. Thank you!' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 12:54:46
DataPoint Un-verified.	brittany cooksey (b) (4)	13 Jan 2021 19:06:10
User entered '1' reason for change: Data Entry Error	brittany cooksey (b) (4)	13 Jan 2021 19:06:10
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '0'	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:34:10
User closed query 'Per CDM: It appears that "Temperature" and "O2 Saturation" are not recorded. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 09:24:16
Query 'Per CDM: It appears that "Temperature" and "O2 Saturation" are not recorded. If not collected, please consider recording these as "Not Done". Thank you!' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	15 Jan 2021 14:28:20
DataPoint Un-verified.	brittany cooksey (b) (4)	15 Jan 2021 14:27:20
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4)	15 Jan 2021 14:27:20
User opened query 'Per CDM: It appears that "Temperature" and "O2 Saturation" are not recorded. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 12:53:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:54:07
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '99'	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:22:52**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User entered '%'	System	15 Jan 2021 14:27:20
User entered empty.	System	10 Nov 2020 14:58:58
User entered '%'	System	27 Oct 2020 18:56:01

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:34:05
User closed query 'Per CDM: It appears that "Temperature" is not recorded. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 08:54:21
Query 'Per CDM: It appears that "Temperature" is not recorded. If not collected, please consider recording these as "Not Done". Thank you!' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	18 Jan 2021 19:30:02
DataPoint Un-verified.	brittany cooksey (b) (4)	18 Jan 2021 19:29:31
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4)	18 Jan 2021 19:29:31
User opened query 'Per CDM: It appears that "Temperature" is not recorded. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 09:24:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:54:13
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '97.9' F	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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Generated On: 11 Aug 2021 22:22:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'Mild (Mild)'	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:54:28
User closed query 'Please review source and revise if needed. Source does not state that subject had nausea on 27Oct2020.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:54:22
Query 'Please review source and revise if needed. Source does not state that subject had nausea on 27Oct2020.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	10 Nov 2020 15:02:19
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 14:43:57
User opened query 'Please review source and revise if needed. Source does not state that subject had nausea on 27Oct2020.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 02:51:54
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 02:50:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'Mild (Mild)'	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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Form: Symptom Log (2)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'Mild (Mild)'	brittany cooksey (b) (4)	27 Oct 2020 18:56:01

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Day 3 (Day 3)'	(b) (4) brittany cooksey (b) (4)	29 Oct 2020 16:26:08

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:54:45
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
User entered '25 Oct 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '28 Oct 2020'	brittany cooksey (b) (4)	29 Oct 2020 16:26:08

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:20
User closed query 'Per CDM: "Assessment Not Done" is checked, however assessments are present. Please update. Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 09:24:26
Query 'Per CDM: "Assessment Not Done" is checked, however assessments are present. Please update. Thank you!' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	15 Jan 2021 14:28:28
User entered '0' reason for change: Data Entry Error	brittany cooksey (b) (4)	15 Jan 2021 14:27:20
User opened query 'Per CDM: "Assessment Not Done" is checked, however assessments are present. Please update. Thank you!' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 12:54:24
DataPoint Un-verified.	brittany cooksey (b) (4)	13 Jan 2021 19:06:35
User entered '1' reason for change: Data Entry Error	brittany cooksey (b) (4)	13 Jan 2021 19:06:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '0'	brittany cooksey (b) (4)	29 Oct 2020 16:26:08

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:22
User closed query 'Per CDM: It appears that "Temperature" and "O2 Saturation" are not recorded. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 09:24:28
Query 'Per CDM: It appears that "Temperature" and "O2 Saturation" are not recorded. If not collected, please consider recording these as "Not Done". Thank you!' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	15 Jan 2021 14:28:32
DataPoint Un-verified.	brittany cooksey (b) (4)	15 Jan 2021 14:27:20
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4)	15 Jan 2021 14:27:20
User opened query 'Per CDM: It appears that "Temperature" and "O2 Saturation" are not recorded. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 12:53:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:54:53
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '99'	brittany cooksey (b) (4)	29 Oct 2020 16:26:08

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**Form: Symptom Log (3)**

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User entered '%'	System	15 Jan 2021 14:27:20
User entered empty.	System	10 Nov 2020 14:58:58
User entered '%'	System	29 Oct 2020 16:26:08

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Form: Symptom Log (3)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:23
User closed query 'Per CDM: It appears that "Temperature" is not recorded. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 08:54:26
Query 'Per CDM: It appears that "Temperature" is not recorded. If not collected, please consider recording these as "Not Done". Thank you!' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	18 Jan 2021 19:30:11
DataPoint Un-verified.	brittany cooksey (b) (4)	18 Jan 2021 19:29:31
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4)	18 Jan 2021 19:29:31
User opened query 'Per CDM: It appears that "Temperature" is not recorded. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 09:24:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:55:04
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '98.1' F	brittany cooksey (b) (4)	29 Oct 2020 16:26:08

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Form: Symptom Log (3)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:26:08

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:26:08

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:26:08

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:26:08

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:26:08

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:55:10
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:57:11
User entered 'Mild (Mild)' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:57:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:26:08

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:26:08

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:26:08

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:26:08

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:26:08

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:26:08

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:26:08

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:26:08

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:26:08

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:26:08

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:55:23
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
User entered 'Mild (Mild)' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:26:08

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Day 4 (Day 4)'	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:55:43
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
User entered '26 Oct 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '29 Oct 2020'	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:42
User closed query 'Per CDM: "Assessment Not Done" is checked, however assessments are present. Please update. Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 09:24:40
Query 'Per CDM: "Assessment Not Done" is checked, however assessments are present. Please update. Thank you!' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	15 Jan 2021 14:28:53
User entered '0' reason for change: Data Entry Error	brittany cooksey (b) (4)	15 Jan 2021 14:27:20
User opened query 'Per CDM: "Assessment Not Done" is checked, however assessments are present. Please update. Thank you!' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 12:54:37
DataPoint Un-verified.	brittany cooksey (b) (4)	13 Jan 2021 19:07:38
User entered '1' reason for change: Data Entry Error	brittany cooksey (b) (4)	13 Jan 2021 19:07:38
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '0'	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 22:45:31
User closed query 'Per CDM re-query: It appears that "O2 Saturation" is not recorded. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 09:24:41
Query 'Per CDM re-query: It appears that "O2 Saturation" is not recorded. If not collected, please consider recording these as "Not Done". Thank you!' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	15 Jan 2021 14:28:58
DataPoint Un-verified.	brittany cooksey (b) (4)	15 Jan 2021 14:27:20
User entered missing code ND - Not Done; reason for change Data Entry Error	brittany cooksey (b) (4)	15 Jan 2021 14:27:20
User opened query 'Per CDM re-query: It appears that "O2 Saturation" is not recorded. If not collected, please consider recording these as "Not Done". Thank you!' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 12:55:20
User closed query 'Per CDM: It appears that O2 Saturation was not provided. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 12:55:20
Query 'Per CDM: It appears that O2 Saturation was not provided. If not collected, please consider recording as Not Done.' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	13 Jan 2021 19:07:52
User opened query 'Per CDM: It appears that O2 Saturation was not provided. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 17:08:27
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:59:49
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '99'	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:22:52**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User entered '%'	System	15 Jan 2021 14:27:20
User entered empty.	System	10 Nov 2020 14:58:58
User entered '%'	System	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:59:54
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
User entered '98.8' F reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '98.2' F	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:00:06
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:57:11
User entered 'Mild (Mild)' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:57:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:00:12
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
User entered 'Mild (Mild)' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	brittany cooksey (b) (4)	29 Oct 2020 16:27:00

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Day 5 (Day 5)'	(b) (4) Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:02:13
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
User entered '27 Oct 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '30 Oct 2020'	Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '0'	Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '99'	Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:22:52**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User entered '%'	System	02 Nov 2020 15:54:30

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:02:19
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
User entered '97.9' F reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '98.2' F	Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:52

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:02:36
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:57:11
User entered 'Mild (Mild)' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:57:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:02:42
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
User entered 'Mild (Mild)' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 15:54:30

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Day 6 (Day 6)'	(b) (4) Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:03:08
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
User entered '28 Oct 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '31 Oct 2020'	Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '0'	Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '99'	Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:22:52**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User entered '%'	System	02 Nov 2020 16:23:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:03:12
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
User entered '98.1' F reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '98.2' F	Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:23:22

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Day 7 (Day 7)'	(b) (4) Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:03:42
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
User entered '29 Oct 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '01 Nov 2020'	Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '0'	Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '99'	Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:22:52**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User entered '%'	System	02 Nov 2020 16:24:34

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Folder: Covid-19 Assessment 26 Oct 2020

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:03:46
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
User entered '98.2' F reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '98.1' F	Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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Form: Symptom Log (7)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	02 Nov 2020 16:24:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Day 8 (Day 8)'	(b) (4) Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:04:07
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
User entered '30 Oct 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '02 Nov 2020'	Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '0'	Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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Form: Symptom Log (8)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:04:12
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
User entered '99' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '98'	Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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**Form: Symptom Log (8)**

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User entered '%'	System	03 Nov 2020 20:32:58

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:04:18
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
User entered '98.2' F reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '98.9' F	Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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Folder: Covid-19 Assessment 26 Oct 2020

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:52

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:04:30
User closed query 'Please review source and revise if needed. Subject did not report body aches during their Day 8 phone contact.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:04:25
Query 'Please review source and revise if needed. Subject did not report body aches during their Day 8 phone contact.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	10 Nov 2020 15:02:50
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 14:57:11
User opened query 'Please review source and revise if needed. Subject did not report body aches during their Day 8 phone contact.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 03:02:16
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 03:01:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'Mild (Mild)'	Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:48:17
User closed query 'The headache was reported on 02Nov2020 phone contact, so please revise the answer to of headache on this day to Non and on 02Nov2020 to Mild.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:48:15
Query 'The headache was reported on 02Nov2020 phone contact, so please revise the answer to of headache on this day to Non and on 02Nov2020 to Mild.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	10 Nov 2020 21:45:02
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 21:44:55
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User opened query 'The headache was reported on 02Nov2020 phone contact, so please revise the answer to of headache on this day to Non and on 02Nov2020 to Mild.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:06:40
User closed query 'Please review source and revise if needed. Subject did report a headache during their Day 8 phone contact.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:06:40
Query 'Please review source and revise if needed. Subject did report a headache during their Day 8 phone contact.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	10 Nov 2020 15:02:57
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 14:55:21
User opened query 'Please review source and revise if needed. Subject did report a headache during their Day 8 phone contact.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 03:02:48
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 03:01:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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Form: Symptom Log (8)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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Form: Symptom Log (8)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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Form: Symptom Log (8)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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Form: Symptom Log (8)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:32:58

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Day 9 (Day 9)'	(b) (4) Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:07:17
User closed query 'Please add from source Day 10, Day 11, Day 12, Day 13, and Day 14.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:06:55
Query 'Please add from source Day 10, Day 11, Day 12, Day 13, and Day 14.' answered with 'updated remaining pages' (Site from CRA).	brittany cooksey (b) (4)	10 Nov 2020 15:10:47
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
User entered '31 Oct 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:55:21
User opened query 'Please add from source Day 10, Day 11, Day 12, Day 13, and Day 14.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 03:05:02
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '03 Nov 2020'	Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

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Folder: Covid-19 Assessment 26 Oct 2020

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '0'	Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:07:22
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
User entered '99' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '100'	Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

**US3302310**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:22:52**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User entered '%'	System	03 Nov 2020 20:33:40

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:07:27
DataPoint Un-verified.	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
User entered '98.2' F reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 14:58:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered '97.5' F	Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:22:52**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:47:19
User entered 'None (None)'	Brittany Belcher (b) (4)	03 Nov 2020 20:33:40

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Day 10 (Day 10)'	(b) (4) brittany cooksey (b) (4)	10 Nov 2020 15:05:16

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:07:51
User entered '01 Nov 2020'	brittany cooksey (b) (4)	10 Nov 2020 15:05:16

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:07:55
User entered '0'	brittany cooksey (b) (4)	10 Nov 2020 15:05:16

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:00
User entered '99'	brittany cooksey (b) (4)	10 Nov 2020 15:05:16

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 22:22:52**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User entered '%'	System	10 Nov 2020 15:05:16

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:05
User entered '98.1' F	brittany cooksey (b) (4)	10 Nov 2020 15:05:16

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:09
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:05:16

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:05:16

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:05:16

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:05:16

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:05:16

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:05:16

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:05:16

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:05:16

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:05:16

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:05:16

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:05:16

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:05:16

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:05:16

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:05:16

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:05:16

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:05:16

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Day 11 (Day 11)'	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered '02 Nov 2020'	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered '0'	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered '98'	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

**US3302310**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:22:52**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User entered '%'	System	10 Nov 2020 15:06:33

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered '98.9' F	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:48:39
User closed query 'Please review source and revise if needed. Source states that subject reported a headache during 02Nov2020 phone call.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:48:37
Query 'Please review source and revise if needed. Source states that subject reported a headache during 02Nov2020 phone call.' answered with 'update' (Site from CRA).	brittany cooksey (b) (4)	10 Nov 2020 21:46:00
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 21:45:44
User opened query 'Please review source and revise if needed. Source states that subject reported a headache during 02Nov2020 phone call.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:09:21
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:06:33

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Day 12 (Day 12)'	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered '03 Nov 2020'	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered '0'	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered '100'	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

**US3302310**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:22:52**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User entered '%'	System	10 Nov 2020 15:07:42

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered '97.5' F	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:07:42

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Day 13 (Day 13)'	(b) (4) brittany cooksey (b) (4)	10 Nov 2020 15:09:06

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered '04 Nov 2020'	brittany cooksey (b) (4)	10 Nov 2020 15:09:06

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered '0'	brittany cooksey (b) (4)	10 Nov 2020 15:09:06

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:49:04
User closed query 'Please review source and revise if needed. Source states: "Subject left message for site. Day 10: Temp 97.6 O2 99%, Day 11: Temp 98.0 O2 99%" Day 10 is 04Nov2020 and Day 11 is 04Nov2020.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:49:03
Query 'Please review source and revise if needed. Source states: "Subject left message for site. Day 10: Temp 97.6 O2 99%, Day 11: Temp 98.0 O2 99%" Day 10 is 04Nov2020 and Day 11 is 04Nov2020.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	10 Nov 2020 21:47:54
User opened query 'Please review source and revise if needed. Source states: "Subject left message for site. Day 10: Temp 97.6 O2 99%, Day 11: Temp 98.0 O2 99%" Day 10 is 04Nov2020 and Day 11 is 04Nov2020.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:11:05
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered '99'	brittany cooksey (b) (4)	10 Nov 2020 15:09:06

**US3302310**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:22:52**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User entered '%'	System	10 Nov 2020 15:09:06

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User closed query 'Please review source and revise if needed. Source states: "Subject left message for site. Day 10: Temp 97.6 O2 99%, Day 11: Temp 98.0 O2 99%" Day 10 is 04Nov2020 and Day 11 is 04Nov2020.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:49:10
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:49:07
Query 'Please review source and revise if needed. Source states: "Subject left message for site. Day 10: Temp 97.6 O2 99%, Day 11: Temp 98.0 O2 99%" Day 10 is 04Nov2020 and Day 11 is 04Nov2020.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	10 Nov 2020 21:47:59
User entered '97.6' F reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 21:47:48
User opened query 'Please review source and revise if needed. Source states: "Subject left message for site. Day 10: Temp 97.6 O2 99%, Day 11: Temp 98.0 O2 99%" Day 10 is 04Nov2020 and Day 11 is 04Nov2020.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:12:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:11:26
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered '98.0' F	brittany cooksey (b) (4)	10 Nov 2020 15:09:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:09:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:09:06

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:09:06

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:09:06

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:09:06

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:09:06

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:09:06

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:09:06

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:09:06

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:09:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:09:06

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:09:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:09:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:09:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:09:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:09:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Day 14 (Day 14)'	(b) (4) brittany cooksey (b) (4)	10 Nov 2020 15:10:17

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered '05 Nov 2020'	brittany cooksey (b) (4)	10 Nov 2020 15:10:17

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered '0'	brittany cooksey (b) (4)	10 Nov 2020 15:10:17

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:49:18
User closed query 'Please review source and revise if needed. Source states: "Subject left message for site. Day 10: Temp 97.6 O2 99%, Day 11: Temp 98.0 O2 99%" Day 10 is 04Nov2020 and Day 11 is 04Nov2020.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:49:15
Query 'Please review source and revise if needed. Source states: "Subject left message for site. Day 10: Temp 97.6 O2 99%, Day 11: Temp 98.0 O2 99%" Day 10 is 04Nov2020 and Day 11 is 04Nov2020.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	10 Nov 2020 21:48:30
User opened query 'Please review source and revise if needed. Source states: "Subject left message for site. Day 10: Temp 97.6 O2 99%, Day 11: Temp 98.0 O2 99%" Day 10 is 04Nov2020 and Day 11 is 04Nov2020.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:13:02
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:12:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered '99'	brittany cooksey (b) (4)	10 Nov 2020 15:10:17

**US3302310**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (14)**

**Generated On: 11 Aug 2021 22:22:52**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User entered '%'	System	10 Nov 2020 15:10:17

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:49:20
User closed query 'Please review source and revise if needed. Source states: "Subject left message for site. Day 10: Temp 97.6 O2 99%, Day 11: Temp 98.0 O2 99%" Day 10 is 04Nov2020 and Day 11 is 04Nov2020.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:49:16
Query 'Please review source and revise if needed. Source states: "Subject left message for site. Day 10: Temp 97.6 O2 99%, Day 11: Temp 98.0 O2 99%" Day 10 is 04Nov2020 and Day 11 is 04Nov2020.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	10 Nov 2020 21:48:34
User entered '98.0' F reason for change: Data Entry Error	(b) (4)	10 Nov 2020 21:48:24
User opened query 'Please review source and revise if needed. Source states: "Subject left message for site. Day 10: Temp 97.6 O2 99%, Day 11: Temp 98.0 O2 99%" Day 10 is 04Nov2020 and Day 11 is 04Nov2020.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:13:12
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:12:52
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered '97.6' F	brittany cooksey (b) (4)	10 Nov 2020 15:10:17

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:10:17

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:10:17

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:10:17

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:10:17

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:10:17

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:10:17

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:10:17

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:10:17

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:10:17

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:10:17

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:10:17

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:10:17

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:10:17

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:10:17

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:10:17

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:52

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:45
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:08:15
User entered 'None (None)'	brittany cooksey (b) (4)	10 Nov 2020 15:10:17

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:52

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:46:14
User entered '26 Oct 2020'	brittany cooksey (b) (4)	26 Oct 2020 14:06:11

**US3302310**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:22:52**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:46:14
User entered 'Yes (Y)'	brittany cooksey (b) (4)	26 Oct 2020 14:06:11

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:52

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:46:14
User closed query 'Per CDM: Please consider entering missing Adverse Event for this Covid-19 case. Thank you!' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:23:57
User closed query 'Please verify as central illness result was negative.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 20:47:56
Query 'Per CDM: Please consider entering missing Adverse Event for this Covid-19 case. Thank you!' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	06 Nov 2020 17:39:54
Query 'Please verify as central illness result was negative.' answered with 'central illness result was negative but subject went and tested outside of study and results were positive days later.' (Site from CRA).	brittany cooksey (b) (4)	06 Nov 2020 17:39:46
User opened query 'Please verify as central illness result was negative.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 05:19:16
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 06:43:11
User opened query 'Per CDM: Please consider entering missing Adverse Event for this Covid-19 case. Thank you!' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:43:10
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'updated' (Site from System).	Wendy Taylor (b) (4)	02 Nov 2020 15:47:08
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 15:47:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Nov 2020 15:47:01
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	02 Nov 2020 15:47:01

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[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	02 Nov 2020 15:47:01
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 14:06:11
User entered empty.	brittany cooksey (b) (4)	26 Oct 2020 14:06:11
	(b) (4)	

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:01:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User closed query 'Per GCL Lab reconciliation requery: Swab: Per PPD portal, swab sample was collected at illness visit on 26-OCT-2020 with accession number # 1F640143054; however, per response, "results have been received. Accession # 1F609GU", corresponding accession number is not present in Preclarus. Please review the Accession # in Preclarus to confirm the correct visit and correct sample label. Also amend EDC or Preclarus as appropriate.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 11:42:19
' (Site from DM). Query 'Per GCL Lab reconciliation requery: Swab: Per PPD portal, swab sample was collected at illness visit on 26-OCT-2020 with accession number # 1F640143054; however, per response, "results have been received. Accession # 1F609GU", corresponding accession number is not present in Preclarus. Please review the Accession # in Preclarus to confirm the correct visit and correct sample label. Also amend EDC or Preclarus as appropriate.	brittany cooksey (b) (4) (b) (4)	03 Feb 2021 14:17:12
' answered with 'Subject had illness day 1 visit on 26oCT2020. The Accession Number from that report is 1F609GU. I know this query keeps going back and forth between 26 or 30 OCT. Please confirm entered is correct' (Site from DM).		
DataPoint Un-verified.	brittany cooksey (b) (4) (b) (4)	03 Feb 2021 14:15:44
User entered '26 Oct 2020' reason for change: Data Entry Error	brittany cooksey (b) (4) (b) (4)	03 Feb 2021 14:15:44

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Generated On: 11 Aug 2021 22:22:52

Date of Test

Audit	User	Time (GMT)
User opened query 'Per GCL Lab reconciliation requery: Swab: Per PPD portal, swab sample was collected at illness visit on 26-OCT-2020 with accession number # 1F640143054; however, per response, "results have been received. Accession # 1F609GU", corresponding accession number is not present in Preclarus. Please review the Accession # in Preclarus to confirm the correct visit and correct sample label. Also amend EDC or Preclarus as appropriate.  ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:17:03
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per response, "Subject did have an illness visit on 26OCT2020 and this has been entered." & per PPD portal, swab sample was collected on 26-OCT-2020; however, per EDC, swab was collected on 30-OCT-2020. Kindly consider updating the date of test as appropriate, if swab sample was collected on 26-OCT-2020, else clarify.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:17:03
Query 'Per GCL Lab Reconciliation requery: Swab: Per response, "Subject did have an illness visit on 26OCT2020 and this has been entered." & per PPD portal, swab sample was collected on 26-OCT-2020; however, per EDC, swab was collected on 30-OCT-2020. Kindly consider updating the date of test as appropriate, if swab sample was collected on 26-OCT-2020, else clarify.' answered with 'results have been received. ACcession # 1F609GU' (Site from DM).	brittany cooksey (b) (4)	01 Feb 2021 20:05:06
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per response, "Subject did have an illness visit on 26OCT2020 and this has been entered." & per PPD portal, swab sample was collected on 26-OCT-2020; however, per EDC, swab was collected on 30-OCT-2020. Kindly consider updating the date of test as appropriate, if swab sample was collected on 26-OCT-2020, else clarify.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 10:20:16

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[Date of Test](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated "30-OCT-2020" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "26-OCT-2020" for Illness visit Day 1. Kindly review the collection date and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 10:20:16
Query 'Per GCL Lab Reconciliation: Swab: Sample dated "30-OCT-2020" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "26-OCT-2020" for Illness visit Day 1. Kindly review the collection date and update as appropriate, else clarify.' answered with 'entered is per query. Subject did have an illness visit on 26OCT2020 and this has been entered.' (Site from DM).	brittany cooksey (b) (4) (b) (4)	27 Jan 2021 20:24:39
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated "30-OCT-2020" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "26-OCT-2020" for Illness visit Day 1. Kindly review the collection date and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 08:16:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:46:14
User entered '30 Oct 2020' reason for change: Data Entry Error	Wendy Taylor (b) (4)	06 Nov 2020 20:08:17
User entered '26 Oct 2020'	brittany cooksey (b) (4) (b) (4)	26 Oct 2020 14:06:11

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Form: COVID Diagnostic Test

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Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:58:03
Query 'Please review source and revise if needed. Source states that subject test positive with their Day 5 Saliva sample and not the Naso Swab.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 22:57:59
User opened query 'Please review source and revise if needed. Source states that subject test positive with their Day 5 Saliva sample and not the Naso Swab.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 22:56:42
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 22:54:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:46:14
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	brittany cooksey (b) (4)	26 Oct 2020 14:06:11

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[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:46:14
User entered empty.	brittany cooksey (b) (4)	26 Oct 2020 14:06:11

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

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[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:46:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	06 Nov 2020 20:08:17
User entered 'No (N)'	brittany cooksey (b) (4)	26 Oct 2020 14:06:11

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:46:14
User entered 'Luxor Scientific' reason for change: Data Entry Error	Wendy Taylor (b) (4)	06 Nov 2020 20:08:17
User entered empty.	brittany cooksey (b) (4)	26 Oct 2020 14:06:11

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:46:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	06 Nov 2020 20:08:17
User entered empty.	brittany cooksey (b) (4)	26 Oct 2020 14:06:11

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**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:22:52**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:51:55
User entered 'I'	System	02 Nov 2020 15:47:01

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:52

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:52

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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Folder: Covid-19 Assessment 26 Oct 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:52

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User closed query 'Per CDM: Please be aware that this question is still not answered. Please answer this question or clarify otherwise. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 11:05:13
Query 'Per CDM: Please be aware that this question is still not answered. Please answer this question or clarify otherwise. Thank you!' answered with 'THE ANSWER WAS NO, THIS ANSWER SHOULD BE LEFT BLANK' (Site from DM).	marsha gossett (b) (4) (b) (4)	14 Nov 2020 04:21:58
User opened query 'Per CDM: Please be aware that this question is still not answered. Please answer this question or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 07:15:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 07:14:50
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:15:26
User closed query 'Please review source and symptom log and revise if needed. Symptom Log does not have a result for Oxygen Saturation and it is not listed in Source notes. If test was not done, then please leave answer blank.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:15:21
Query 'Data is required. Please complete.' answered with 'updated' (Site from System).	brittany cooksey (b) (4) (b) (4)	10 Nov 2020 15:43:19
Query 'Please review source and symptom log and revise if needed. Symptom Log does not have a result for Oxygen Saturation and it is not listed in Source notes. If test was not done, then please leave answer blank.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4) (b) (4)	10 Nov 2020 15:43:14
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 15:42:58
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4) (b) (4)	10 Nov 2020 15:42:58

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Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
User opened query 'Please review source and symptom log and revise if needed. Symptom Log does not have a result for Oxygen Saturation and it is not listed in Source notes. If test was not done, then please leave answer blank.' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 01:58:21
	(b) (4), (b) (6)	10 Nov 2020 01:56:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 17:45:10
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

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Generated On: 11 Aug 2021 22:22:52

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:52

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

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Generated On: 11 Aug 2021 22:22:52

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

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Generated On: 11 Aug 2021 22:22:52

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:52

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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Folder: Covid-19 Assessment 26 Oct 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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Folder: Covid-19 Assessment 26 Oct 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:52

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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Folder: Covid-19 Assessment 26 Oct 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:52

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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Folder: Covid-19 Assessment 26 Oct 2020

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Generated On: 11 Aug 2021 22:22:52

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:52

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

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Generated On: 11 Aug 2021 22:22:52

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:52

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:03
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:56:20
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:45:10

US3302310

Folder: Covid-19 Assessment 26 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:22:52

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:52:09
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 13:07:22
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	02 Nov 2020 15:43:35

**US3302310**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

**US3302310**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:15:01
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

US3302310

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:22:52

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28OCT2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 08:47:50
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28OCT2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'samples shipped and results received' (Site from DM).	brittany cooksey (b) (4) (b) (4)	08 Dec 2020 18:58:18
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28OCT2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 10:42:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:15:03
User entered '28 Oct 2020'	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

US3302310

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:22:52

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 08:47:54
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'samples shipped and results received' (Site from DM).	brittany cooksey (b) (4) (b) (4)	08 Dec 2020 18:58:33
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 10:42:54
User accepted default value 'Day 5 (Day 5)'	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

**US3302310**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:15:18
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

**US3302310**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:15:20
User entered '30 Oct 2020'	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

US3302310

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:22:52

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01,03NOV2020 is recorded under Illness Visit Day 7,9 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:00:36
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01,03NOV2020 is recorded under Illness Visit Day 7,9 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'samples shipped and results received' (Site from DM).	brittany cooksey (b) (4) (b) (4)	08 Dec 2020 18:58:45
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01,03NOV2020 is recorded under Illness Visit Day 7,9 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 10:43:10
User accepted default value 'Day 7 (Day 7)'	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

**US3302310**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:16:14
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

**US3302310**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:16:16
User entered '1 Nov 2020'	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

**US3302310**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

**US3302310**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:54
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

**US3302310**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:17:56
User entered '3 Nov 2020'	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

US3302310

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:22:52

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15NOV2020 is reported under Illness visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 04:24:01
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15NOV2020 is reported under Illness visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 13:25:55
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15NOV2020 is reported under Illness visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 05:21:35
User accepted default value 'Day 14 (Day 14)'	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

US3302310

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:22:52

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 17:22:29
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 15:41:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 15:41:59
User entered 'Yes (Y)' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 15:41:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:33:37
User entered empty.	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

US3302310

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:22:52

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User closed query 'Please review source and revise if needed. Source states that Day 14 Saliva sample was collected on 08Nov2020.' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 14:56:03
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 14:56:00
Query 'Please review source and revise if needed. Source states that Day 14 Saliva sample was collected on 08Nov2020.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	08 Dec 2020 18:59:23
User entered '08 Nov 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	08 Dec 2020 18:59:16
User opened query 'Please review source and revise if needed. Source states that Day 14 Saliva sample was collected on 08Nov2020.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 14:50:46
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 13:25:50
User entered '15 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 13:25:50
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:22:32
User entered '08 Nov 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 15:41:59
User entered empty.	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

**US3302310**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:22:52**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

US3302310

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:22:52

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 14:51:22
User closed query 'Day 21 was on 15Nov2020, so please review source and revise if needed. Source states that the Saliva Sample was collected on 15Nov2020.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 14:51:19
Query 'Day 21 was on 15Nov2020, so please review source and revise if needed. Source states that the Saliva Sample was collected on 15Nov2020.' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 13:26:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 13:26:29
User opened query 'Day 21 was on 15Nov2020, so please review source and revise if needed. Source states that the Saliva Sample was collected on 15Nov2020.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 18:41:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 07:13:17
Query 'Data is required. Please complete.' answered with 'Day 21 has not yet occurred' (Site from System).	brittany cooksey (b) (4)	10 Nov 2020 15:42:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	06 Nov 2020 20:33:37
	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

**US3302310**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:22:52**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 14:51:24
User entered '15 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 13:26:29
User entered empty.	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

**US3302310**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:22:52**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

US3302310

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:22:52

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 22:51:24
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 22:47:20
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 14:52:09
User closed query 'Day 28 occurred on 23Nov2020 - please review source and revise if needed. Source states that subject had a Nasal Swab collected during the Day 28 visit.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 14:52:06
Query 'Day 28 occurred on 23Nov2020 - please review source and revise if needed. Source states that subject had a Nasal Swab collected during the Day 28 visit.' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 13:27:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 13:27:07
User opened query 'Day 28 occurred on 23Nov2020 - please review source and revise if needed. Source states that subject had a Nasal Swab collected during the Day 28 visit.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 18:39:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 07:13:20
Query 'Data is required. Please complete.' answered with 'Day 28 has not yet occurred' (Site from System).	brittany cooksey (b) (4)	10 Nov 2020 15:42:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	06 Nov 2020 20:33:37
User entered empty.	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

US3302310

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:22:52

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23NOV2020 is recorded under Illness Visit Day 28 visit in EDC, however the data is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you. '(Site from DM).	(b) (4), (b) (6)	19 Jan 2021 08:52:14
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23NOV2020 is recorded under Illness Visit Day 28 visit in EDC, however the data is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you. ' answered with 'correct visit is day 28' (Site from DM).	brittany cooksey (b) (4)	06 Jan 2021 02:46:43
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23NOV2020 is recorded under Illness Visit Day 28 visit in EDC, however the data is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you. '(Site from DM).	(b) (4), (b) (6)	10 Dec 2020 02:18:35
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 14:52:12
User entered '23 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 13:27:07
User entered empty.	Wendy Taylor (b) (4)	06 Nov 2020 20:33:37

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:09:47
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	06 Nov 2020 20:24:24

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:09:47
User entered '26 Oct 2020'	Wendy Taylor (b) (4)	06 Nov 2020 20:24:24

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:09:47
User entered 'Clinic (Clinic)'	Wendy Taylor (b) (4)	06 Nov 2020 20:24:24

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User entered 'SICKD1'	System	06 Nov 2020 20:24:24

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:10:30
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	06 Nov 2020 20:30:43

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:10:30
User entered '26 Oct 2020'	Wendy Taylor (b) (4)	06 Nov 2020 20:30:43

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:10:30
User entered '09:30'	Wendy Taylor (b) (4)	06 Nov 2020 20:30:43

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User entered '26 Oct 2020 09:30'	System	06 Nov 2020 20:30:43

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:10:30
User entered '69' in	Wendy Taylor (b) (4)	06 Nov 2020 20:30:43
DataPoint set to visible.	System	06 Nov 2020 20:24:24

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:10:30
User entered '130' lb	Wendy Taylor (b) (4)	06 Nov 2020 20:30:43
DataPoint set to visible.	System	06 Nov 2020 20:24:24

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:10:30
User entered '98.8' F	Wendy Taylor (b) (4)	06 Nov 2020 20:30:43

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:10:30
User entered 'Oral (Oral)'	Wendy Taylor (b) (4)	06 Nov 2020 20:30:43

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:10:30
User entered empty.	Wendy Taylor (b) (4)	06 Nov 2020 20:30:43

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:10:30
User entered '80'	Wendy Taylor (b) (4)	06 Nov 2020 20:30:43

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User entered 'bpm'	System	06 Nov 2020 20:30:43

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:10:30
User entered '18'	Wendy Taylor (b) (4)	06 Nov 2020 20:30:43

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User entered 'breaths/min'	System	06 Nov 2020 20:30:43

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:10:30
User entered '108'	Wendy Taylor (b) (4)	06 Nov 2020 20:30:43

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User entered 'mmHg'	System	06 Nov 2020 20:30:43

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:10:30
User entered '78'	Wendy Taylor (b) (4)	06 Nov 2020 20:30:43

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User entered 'mmHg'	System	06 Nov 2020 20:30:43

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:22:52**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:12:12
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	06 Nov 2020 20:30:55

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:22:52**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:12:12
User entered '26 Oct 2020'	Wendy Taylor (b) (4)	06 Nov 2020 20:30:55

US3302310

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:22:52

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:12:27
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	06 Nov 2020 20:31:05

**US3302310**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 22:22:52**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:18:31
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:12:27
User entered '26 Oct 2020'	Wendy Taylor (b) (4)	06 Nov 2020 20:31:05

US3302310

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:22:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23NOV2020 is reported under Unscheduled visit in PPD Central lab, Please review if the Immuno sample was also collected as Unscheduled visit. If yes, then the Immuno sample data will be updated under UNSCHEDULED visit on the Immunogenicity assessment form. If not collected, then confirm in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 06:13:34
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23NOV2020 is reported under Unscheduled visit in PPD Central lab, Please review if the Immuno sample was also collected as Unscheduled visit. If yes, then the Immuno sample data will be updated under UNSCHEDULED visit on the Immunogenicity assessment form. If not collected, then confirm in the response. Thank you.' answered with 'that should be for illness visit 28' (Site from DM).	Wendy Taylor (b) (4)	23 Dec 2020 20:18:44
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23NOV2020 is reported under Unscheduled visit in PPD Central lab, Please review if the Immuno sample was also collected as Unscheduled visit. If yes, then the Immuno sample data will be updated under UNSCHEDULED visit on the Immunogenicity assessment form. If not collected, then confirm in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 07:28:42
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:35:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 21:23:49

US3302310

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:22:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "this was entered" per PPD portal swab sample was collected at Covid-19 Assessment on 23 NOV 2020, however, swab sample for 23 NOV 2020 is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating swab data in the COVID Diagnostic form as we do not have provision to capture swab samples on Convalescent Visit Day 28 or Unscheduled eCRF, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 06:20:15
Query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "this was entered" & per PPD portal swab sample was collected at Covid-19 Assessment on 23 NOV 2020, however, swab sample for 23 NOV 2020 is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating swab data in the COVID Diagnostic form as we do not have provision to capture swab samples on Convalescent Visit Day 28 or Unscheduled eCRF, else clarify.' answered with 'confirmed eCRF is completed for day 28' (Site from DM).	brittany cooksey (b) (4) (b) (4)	06 Jan 2021 02:47:39
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "this was entered" per PPD portal swab sample was collected at Covid-19 Assessment on 23 NOV 2020, however, swab sample for 23 NOV 2020 is missing in EDC. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date and updating swab data in the COVID Diagnostic form as we do not have provision to capture swab samples on Convalescent Visit Day 28 or Unscheduled eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 05:50:32

US3302310

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:22:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query ' Per GCL Lab Reconciliation: Swab: Re-Queried: Response noted, however, Covid Diagnostic Test form for the corresponding date 23NOV2020 is not entered. Please update. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 05:50:32
Query ' Per GCL Lab Reconciliation: Swab: Re-Queried: Response noted, however, Covid Diagnostic Test form for the corresponding date 23NOV2020 is not entered. Please update. Thank you.' answered with 'this was entered' (Site from DM).	Wendy Taylor (b) (4)	23 Dec 2020 20:19:15
User opened query ' Per GCL Lab Reconciliation: Swab: Re-Queried: Response noted, however, Covid Diagnostic Test form for the corresponding date 23NOV2020 is not entered. Please update. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 10:48:01
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 23-NOV-2020 is reported under Unscheduled visit in PPD portal; however, the corresponding swab sample is missing in EDC for date 23-NOV-2020. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date, else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 10:48:01
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 23-NOV-2020 is reported under Unscheduled visit in PPD portal; however, the corresponding swab sample is missing in EDC for date 23-NOV-2020. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date, else clarify.' answered with 'added today' (Site from DM).	brittany cooksey (b) (4)	08 Dec 2020 18:57:47
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 23-NOV-2020 is reported under Unscheduled visit in PPD portal; however, the corresponding swab sample is missing in EDC for date 23-NOV-2020. Kindly review if the swab sample was collected, if yes, consider updating EDC by initiating Covid -19 Assessment eCRF for the corresponding date, else clarify.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 12:08:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:35:14

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EAB) (1725)

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**US3302310**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
User entered '23 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 21:23:49

US3302310

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:35:14
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	23 Nov 2020 21:23:49

**US3302310**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User entered 'SICKD28'	System	23 Nov 2020 21:23:49

**US3302310**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:35:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 21:24:37

US3302310

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:35:34
User entered '23 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 21:24:37

**US3302310**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:35:34
User entered '16:15'	(b) (4), (b) (6)	23 Nov 2020 21:24:37

**US3302310**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User entered '23 Nov 2020 16:15'	System	23 Nov 2020 21:24:37

US3302310

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:35:34
User entered '69' in	(b) (4), (b) (6)	23 Nov 2020 21:24:37
DataPoint set to visible.	System	23 Nov 2020 21:23:49

US3302310

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:52

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:35:34
User entered '124' lb	(b) (4), (b) (6)	23 Nov 2020 21:24:37
DataPoint set to visible.	System	23 Nov 2020 21:23:49

US3302310

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:35:34
User entered '97.7' F	(b) (4), (b) (6)	23 Nov 2020 21:24:37

**US3302310**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:35:34
User entered 'Oral (Oral)'	(b) (4), (b) (6)	23 Nov 2020 21:24:37

**US3302310**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:35:34
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 21:24:37

**US3302310**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:35:34
User entered '63'	(b) (4), (b) (6)	23 Nov 2020 21:24:37

**US3302310**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User entered 'bpm'	System	23 Nov 2020 21:24:37

**US3302310**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:35:34
User entered '18'	(b) (4), (b) (6)	23 Nov 2020 21:24:37

**US3302310**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User entered 'breaths/min'	System	23 Nov 2020 21:24:37

US3302310

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:35:34
User entered '123'	(b) (4), (b) (6)	23 Nov 2020 21:24:37

**US3302310**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User entered 'mmHg'	System	23 Nov 2020 21:24:37

US3302310

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:35:34
User entered '76'	(b) (4), (b) (6)	23 Nov 2020 21:24:37

**US3302310**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User entered 'mmHg'	System	23 Nov 2020 21:24:37

**US3302310**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38

**US3302310**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38

US3302310

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:22:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:36:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 21:24:42

US3302310

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:22:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:36:40
User entered '23 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 21:24:42

US3302310

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:22:52

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:43:07
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:36:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 21:24:56

US3302310

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:22:52

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:38
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:43:07
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Thank you for providing the Accession number , Please also provide the Tracking number with the shipping date for the 23 NOV 2020 SARS-CoV-2 serum sample reported under Convalescence Visit Day 28 in EDC, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' (Site from DM). Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Thank you for providing the Accession number , Please also provide the Tracking number with the shipping date for the 23 NOV 2020 SARS-CoV-2 serum sample reported under Convalescence Visit Day 28 in EDC, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' answered with 'will locate number' (Site from DM).	(b) (4) (b) (4), (b) (6) Wendy Taylor (b) (4)	05 Mar 2021 08:13:57 04 Mar 2021 23:35:04
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Thank you for providing the Accession number , Please also provide the Tracking number with the shipping date for the 23 NOV 2020 SARS-CoV-2 serum sample reported under Convalescence Visit Day 28 in EDC, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 08:52:33
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per previous query response, Since the sample was shipped, please provide the Accession number and Tracking number with the shipping date for the 23 NOV 2020 SARS-CoV-2 serum sample reported under Convalescence Visit Day 28, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 11:44:41

US3302310

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:22:52

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per previous query response, Since the sample was shipped, please provide the Accession number and Tracking number with the shipping date for the 23 NOV 2020 SARS-CoV-2 serum sample reported under Convalescence Visit Day 28, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' answered with 'Accession Number: 1F609GU' (Site from DM).	brittany cooksey (b) (4)	11 Jan 2021 20:33:12
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per previous query response, Since the sample was shipped, please provide the Accession number and Tracking number with the shipping date for the 23 NOV 2020 SARS-CoV-2 serum sample reported under Convalescence Visit Day 28, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 07:19:55
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 NOV 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 09:33:02
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 NOV 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'all samples have been shipped' (Site from DM).	brittany cooksey (b) (4)	08 Dec 2020 18:56:13

US3302310

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:22:52

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 NOV 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 08:10:12
	(b) (4), (b) (6)	24 Nov 2020 18:36:47
User entered '23 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 21:24:56

**US3302310**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 17:58:22

**US3302310**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:58:22

**US3302310**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:58:22

**US3302310**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered 'UNBLND_DECIDE'	System	27 Jan 2021 17:58:22

US3302310

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

Form: Unblinding

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:43
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:21:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '26 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 17:58:34

**US3302310**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:22:52**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:43
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:21:48
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:33:42
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 22:13:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:22:06

US3302310

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

Form: Unblinding

Generated On: 11 Aug 2021 22:22:52

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:43
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:21:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 17:58:34

US3302310

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

Form: Unblinding

Generated On: 11 Aug 2021 22:22:52

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:43
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:21:48
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:33:42
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 10:34:53
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 22:13:41
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 22:13:28
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:11:24
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:22:06

**US3302310**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:22:52**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:43
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:21:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '26 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 17:58:34

US3302310

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

Form: Unblinding

Generated On: 11 Aug 2021 22:22:52

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:43
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:21:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	27 Jan 2021 17:58:34

**US3302310**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:22:52**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:43
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:21:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	27 Jan 2021 17:58:34

**US3302310**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:22:52**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:43
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:21:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	27 Jan 2021 17:58:34

**US3302310**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:22:52**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:43
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:21:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 17:58:34

**US3302310**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:22:52**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:43
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:21:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered 'I'	System	27 Jan 2021 17:58:34

**US3302310**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:22:52**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:43
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 11:21:48
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered 'I'	System	27 Jan 2021 17:58:34

**US3302310**

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

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:22:52**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:59:44

US3302310

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:22:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:22:52**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered empty.	System	27 Jan 2021 17:59:44
DataPoint set to visible.	System	27 Jan 2021 17:58:34

**US3302310**

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

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:22:52**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:59:44

US3302310

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:22:52

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:22:52**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered empty.	System	27 Jan 2021 17:59:44
DataPoint set to visible.	System	27 Jan 2021 17:58:34

**US3302310**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	27 Jan 2021 17:59:44

US3302310

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '26 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '15:36'	(b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered '26 Jan 2021 15:36'	System	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '98.2' F	(b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '81'	(b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered 'bpm'	System	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '16'	(b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered 'breaths/min'	System	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '132'	(b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered 'mmHg'	System	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '79'	(b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered 'mmHg'	System	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:22:52**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:22:52**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:22:52**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered empty.	System	27 Jan 2021 17:59:44
DataPoint set to visible.	System	27 Jan 2021 17:58:34

**US3302310**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '26 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '16:12'	(b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered '26 Jan 2021 16:12'	System	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '99.3' F	(b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '80'	(b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered 'bpm'	System	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '16'	(b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered 'breaths/min'	System	27 Jan 2021 17:59:44

US3302310

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '121'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered 'mmHg'	System	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '75'	(b) (4), (b) (6)	27 Jan 2021 17:59:44

**US3302310**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered 'mmHg'	System	27 Jan 2021 17:59:44

US3302310

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:22:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 12:53:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 12:53:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:59:50

US3302310

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:22:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 12:53:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 12:53:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:59:50

US3302310

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:22:52

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 17:59:57

US3302310

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:22:52

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '26 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 17:59:57

**US3302310**

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

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:59:57

**US3302310**

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

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:59:57

**US3302310**

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

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'No (N)'	(b) (4), (b) (6)	27 Jan 2021 17:59:57

**US3302310**

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

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:59:57

**US3302310**

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

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:59:57

**US3302310**

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

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered empty.	System	27 Jan 2021 17:59:57

**US3302310**

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

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:00:06

**US3302310**

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

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:00:06

US3302310

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

Form: Exposure

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:00:06

**US3302310**

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

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered 'mRNA-1273'	System	27 Jan 2021 18:00:06
DataPoint set to visible.	System	27 Jan 2021 17:58:34

US3302310

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

Form: Exposure

Generated On: 11 Aug 2021 22:22:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User closed query 'Per CDMRQ: please review date in IRT and update accordingly' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 05:21:16
Query 'Per CDMRQ: please review date in IRT and update accordingly' answered with 'Per IWRS, data entered is correct.' (Site from DM).	Brittany Belcher (b) (4)	15 Apr 2021 16:19:21
User opened query 'Per CDMRQ: please review date in IRT and update accordingly' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 16:10:44
User closed query 'Per IRT, Subject had Open Label Day1 Treatment on 27JAN2021. Please review and reconcile.	(b) (4), (b) (6)	15 Apr 2021 16:10:44
' (Site from DM).		
Query 'Per IRT, Subject had Open Label Day1 Treatment on 27JAN2021. Please review and reconcile.	Brittany Belcher (b) (4)	12 Apr 2021 14:05:10
' answered with 'Per source, OL Visit Day 1 occurred on 26JAN2021. Data entered is correct.' (Site from DM).		
User opened query 'Per IRT, Subject had Open Label Day1 Treatment on 27JAN2021. Please review and reconcile.	(b) (4), (b) (6)	09 Apr 2021 09:20:10
' (Site from DM).		
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '26 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 18:00:06

US3302310

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

Form: Exposure

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '15:40'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:00:06

**US3302310**

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

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered '26 Jan 2021 15:40'	System	27 Jan 2021 18:00:06

**US3302310**

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

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:00:06

**US3302310**

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

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered 'ONCE'	System	27 Jan 2021 18:00:06

**US3302310**

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

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered 'INTRAMUSCULAR'	System	27 Jan 2021 18:00:06

**US3302310**

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

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 17:58:45

**US3302310**

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

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '26 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 17:58:45

**US3302310**

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

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '15:17'	(b) (4), (b) (6)	27 Jan 2021 17:58:45

**US3302310**

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

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered '26 Jan 2021 15:17'	System	27 Jan 2021 17:58:45

**US3302310**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:22:52**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:58:53

**US3302310**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:22:52**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '26 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 17:58:53

**US3302310**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:22:52**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '15:15'	(b) (4), (b) (6)	27 Jan 2021 17:58:53

**US3302310**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered '26 Jan 2021 15:15'	System	27 Jan 2021 17:58:53

US3302310

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

Form: Continuing

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:00:44

**US3302310**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:18
User entered 'I'	System	27 Jan 2021 18:00:44

**US3302310**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:37
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
	(b) (4)	
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	02 Feb 2021 13:40:40

US3302310

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:37
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
	(b) (4)	
User entered '02 Feb 2021' reason for change: Data Entry Error	Wendy Taylor (b) (4)	02 Feb 2021 14:08:55
User entered '2 Feb 2021'	Wendy Taylor (b) (4)	02 Feb 2021 13:40:40

**US3302310**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:37
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Wendy Taylor (b) (4)	02 Feb 2021 13:40:40

US3302310

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:37
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
	(b) (4)	
User entered empty.	Wendy Taylor (b) (4)	02 Feb 2021 13:40:40

US3302310

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:37
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
	(b) (4)	
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	02 Feb 2021 13:40:46

**US3302310**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:37
User entered 'I'	System	02 Feb 2021 13:40:46

**US3302310**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:40:37
User entered 'I'	System	02 Feb 2021 13:40:46
DataPoint set to visible.	System	02 Feb 2021 13:40:46

**US3302310**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 23:19:49

**US3302310**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:19:49

**US3302310**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:19:49

**US3302310**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User entered 'OLD29'	System	24 Feb 2021 23:19:49

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered '24 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered '15:58'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User entered '24 Feb 2021 15:58'	System	24 Feb 2021 23:21:07

US3302310

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered '97.3' F	(b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered '71'	(b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User entered 'bpm'	System	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered '16'	(b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User entered 'breaths/min'	System	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered '114'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User entered 'mmHg'	System	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered '81'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User entered 'mmHg'	System	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered '16:33'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User entered '24 Feb 2021 16:33'	System	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered '97.3' F	(b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered '62'	(b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User entered 'bpm'	System	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered '16'	(b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User entered 'breaths/min'	System	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered '121'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User entered 'mmHg'	System	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered '85'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User entered 'mmHg'	System	24 Feb 2021 23:21:07

**US3302310**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:22:52**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:20:27

**US3302310**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:22:52**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered '24 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 23:20:27

**US3302310**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:21:15

**US3302310**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered '24 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 23:21:15

**US3302310**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:21:15

**US3302310**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:21:15

**US3302310**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:21:15

**US3302310**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 23:21:15

**US3302310**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:21:15

**US3302310**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User entered empty.	System	24 Feb 2021 23:21:15

**US3302310**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:21:26

**US3302310**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 23:21:26

US3302310

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 23:21:26

**US3302310**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User entered 'mRNA-1273'	System	24 Feb 2021 23:21:26
DataPoint set to visible.	System	02 Feb 2021 13:40:46

US3302310

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:22:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:21:26

**US3302310**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered '16:02'	(b) (4), (b) (6)	24 Feb 2021 23:21:26

**US3302310**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User entered '24 Feb 2021 16:02'	System	24 Feb 2021 23:21:26

US3302310

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:21:26

**US3302310**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User entered 'ONCE'	System	24 Feb 2021 23:21:26

**US3302310**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:22:52**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User entered 'INTRAMUSCULAR'	System	24 Feb 2021 23:21:26

**US3302310**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 23:21:31

**US3302310**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:47:41
User entered 'I'	System	24 Feb 2021 23:21:31

**US3302310**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:44
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	03 Mar 2021 13:32:52

**US3302310**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:44
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered '03 Mar 2021'	Kendal Nelson (b) (4)	03 Mar 2021 13:32:52

**US3302310**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:44
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered 'Contact Made (CONTACT MADE)'	Kendal Nelson (b) (4)	03 Mar 2021 13:32:52

**US3302310**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:22:52**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:44
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered empty.	Kendal Nelson (b) (4)	03 Mar 2021 13:32:52

**US3302310**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:44
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:56:35
User entered 'Yes (Y)'	Kendal Nelson (b) (4)	03 Mar 2021 13:32:41

**US3302310**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:22:52**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:44
User entered 'I'	System	03 Mar 2021 13:32:41

**US3302310**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 20:19:30

**US3302310**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:19:30

**US3302310**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Mar 2021 20:19:30

**US3302310**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:52**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User entered 'OLD57'	System	24 Mar 2021 20:19:30

**US3302310**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:19:47

**US3302310**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered '23 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 20:19:47

**US3302310**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered '15:54'	(b) (4), (b) (6)	24 Mar 2021 20:19:47

**US3302310**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User entered '23 Mar 2021 15:54'	System	24 Mar 2021 20:19:47

**US3302310**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered '98.4' F	(b) (4), (b) (6)	24 Mar 2021 20:19:47

**US3302310**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Mar 2021 20:19:47

**US3302310**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 20:19:47

**US3302310**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered '69'	(b) (4), (b) (6)	24 Mar 2021 20:19:47

**US3302310**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User entered 'bpm'	System	24 Mar 2021 20:19:47

**US3302310**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered '18'	(b) (4), (b) (6)	24 Mar 2021 20:19:47

**US3302310**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User entered 'breaths/min'	System	24 Mar 2021 20:19:47

**US3302310**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered '123'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:19:47

**US3302310**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User entered 'mmHg'	System	24 Mar 2021 20:19:47

**US3302310**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered '80'	(b) (4), (b) (6)	24 Mar 2021 20:19:47

**US3302310**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User entered 'mmHg'	System	24 Mar 2021 20:19:47

**US3302310**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18

**US3302310**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:52**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18

**US3302310**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:22:52**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:19:51

**US3302310**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:22:52**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 20:19:51

**US3302310**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 20:19:57

**US3302310**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered '23 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 20:19:57

**US3302310**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:19:51
User entered '15:56'	(b) (4), (b) (6)	24 Mar 2021 20:19:57

**US3302310**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:18
User entered '23 Mar 2021 15:56'	System	24 Mar 2021 20:19:57

US3302310

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:22:52

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:13:13
User closed query 'Per DM CLR: Per Day 208 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 07:09:52
Query 'Per DM CLR: Per Day 208 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'Subject was contacted and reported pregnancy. Pregnancy form already reported and sent in to Moderna Safety. ' (Site from DM).	Brittany Belcher (b) (4)	26 Mar 2021 19:01:26
User opened query 'Per DM CLR: Per Day 208 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 14:05:24
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:24:15
User closed query 'Please reconcile and add AE of COVID-19. As a reminder positive illness samples are to be recorded within 24 hrs of sites knowledge' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 04:09:23

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:22:52

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Please reconcile and add AE of COVID-19. As a reminder positive illness samples are to be recorded within 24 hrs of sites knowledge' answered with 'subject results came in as negative. However she did report testing positive outside of trial' (Site from CRA).	brittany cooksey (b) (4) (b) (4)	06 Nov 2020 17:38:40
User opened query 'Please reconcile and add AE of COVID-19. As a reminder positive illness samples are to be recorded within 24 hrs of sites knowledge' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 01:23:06
User entered 'Yes (Y)'	brittany cooksey (b) (4) (b) (4)	26 Oct 2020 14:16:37

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:25:55
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:13:57
User entered		
'USA-US087-2020-mRNA-1273-P301000004'	System	09 Nov 2020 20:13:52
User entered 'New'	(b) (4), (b) (6)	09 Nov 2020 20:13:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 17:44:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 17:44:19
Data point term sent to Coder	System	06 Nov 2020 17:43:44
User entered 'COVID-19'	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered 'Yes (Y)'	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:32:26
User closed query 'PV Query: The symptom started and swab specimen which was positive for SARS-COV-2 was taken on 26-OCT-2020,. Please confirm the event start date is 26-OCT-2020. If not, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 23:57:49
Query 'PV Query: The symptom started and swab specimen which was positive for SARS-COV-2 was taken on 26-OCT-2020,. Please confirm the event start date is 26-OCT-2020. If not, please state so.' answered with 'CORRECTED PER QUERY' (Site from Safety).	marsha gossett (b) (4)	14 Nov 2020 04:09:08
	(b) (4)	
DataPoint Un-verified.	marsha gossett (b) (4)	14 Nov 2020 04:07:58
	(b) (4)	
User entered '26 Oct 2020' reason for change: Data Entry Error	marsha gossett (b) (4)	14 Nov 2020 04:07:58
	(b) (4)	
User opened query 'PV Query: The symptom started and swab specimen which was positive for SARS-COV-2 was taken on 26-OCT-2020,. Please confirm the event start date is 26-OCT-2020. If not, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:05:56
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered '01 Nov 2020'	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:32:34
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 18:32:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:42:56

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:32:35
DataPoint Un-verified.	marsha gossett (b) (4)	14 Nov 2020 04:18:22
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	marsha gossett (b) (4)	14 Nov 2020 04:18:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered 'Yes (Y)'	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:32:37
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 23:58:17
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'CORRECTED' (Site from Safety).	marsha gossett (b) (4)	14 Nov 2020 04:18:34
DataPoint Un-verified.	(b) (4)	
	marsha gossett (b) (4)	14 Nov 2020 04:18:22
User entered '05 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	marsha gossett (b) (4)	14 Nov 2020 04:18:22
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:05:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered empty.	(b) (4)	
	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:42:56

US3302310

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:52

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:37:59
User closed query 'Please review source and revise if needed. Source states that Intensity is "Moderate or Grade 2".' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:37:58
Query 'Please review source and revise if needed. Source states that Intensity is "Moderate or Grade 2".' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	10 Nov 2020 15:45:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 15:44:57
User opened query 'Please review source and revise if needed. Source states that Intensity is "Moderate or Grade 2".' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 02:33:10
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered 'Grade 1/Mild (Grade 1/Mild)'	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered 'No (N)'	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered '0'	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered '0'	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered '0'	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered '0'	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered '0'	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered '0'	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered 'Not Related (NOT RELATED)'	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:32:51
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.	(b) (4), (b) (6)	23 Nov 2020 13:07:52
' (Site from DM).		
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.	brittany cooksey (b) (4)	23 Nov 2020 01:53:01
' answered with 'updated' (Site from DM).	(b) (4)	
DataPoint Un-verified.	brittany cooksey (b) (4)	23 Nov 2020 01:52:52
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	brittany cooksey (b) (4)	23 Nov 2020 01:52:52
reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.	(b) (4), (b) (6)	18 Nov 2020 07:29:46
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered 'Not Applicable (NOT APPLICABLE)'	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered 'Not Applicable (NOT APPLICABLE)'	brittany cooksey (b) (4) (b) (4)	06 Nov 2020 17:42:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:52

None

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:32:54
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#3) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 06:07:50
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#3) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'updated' (Site from DM).	Wendy Taylor (b) (4)	24 Nov 2020 02:13:03
DataPoint Un-verified.	Wendy Taylor (b) (4)	24 Nov 2020 02:12:57
User entered '0' reason for change: Data Entry Error	Wendy Taylor (b) (4)	24 Nov 2020 02:12:57
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#3) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:07:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered '1'	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

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Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:33:32
DataPoint Un-verified.	Wendy Taylor (b) (4)	24 Nov 2020 02:12:57
User entered '1' reason for change: Data Entry Error	Wendy Taylor (b) (4)	24 Nov 2020 02:12:57
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered '0'	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered '0'	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:52

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:33:40
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 23:58:40
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'UPDATED' (Site from Safety).	marsha gossett (b) (4)	14 Nov 2020 04:18:41
DataPoint Un-verified.	(b) (4)	
	marsha gossett (b) (4)	14 Nov 2020 04:18:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	marsha gossett (b) (4)	14 Nov 2020 04:18:22
Data Entry Error	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:05:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 17:43:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 17:43:34
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	brittany cooksey (b) (4)	06 Nov 2020 17:43:34
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 17:42:56
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered empty.	brittany cooksey (b) (4) (b) (4)	06 Nov 2020 17:42:56

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:52

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
User closed query 'PV Query: Please clarify whether the subject had occupational/living and circumstances or occasions for exposure to SARS-COV-2. If not, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 23:59:35
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 23:59:25
User closed query 'PV Query: Indication for Tylenol states Advil. Please clarify indication for Tylenol.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 23:59:22
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 23:59:16
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'ONLY OVER THE COUNTER ADVIL WAS GIVE TO TREAT COVID SYMPTOM OF HEADACHE' (Site from Safety).	marsha gossett (b) (4) (b) (4)	14 Nov 2020 04:14:34
Query 'PV Query: Indication for Tylenol states Advil. Please clarify indication for Tylenol.' answered with 'ADVIL WAS TAKEN FOR HEADACHE (COVID SYMPTOM) I DO NOT SEE WHERE IT STATES TYLENOL STATES ADVIL' (Site from Safety).	marsha gossett (b) (4) (b) (4)	14 Nov 2020 04:14:10
Query 'PV Query: Please clarify whether the subject had occupational/living and circumstances or occasions for exposure to SARS-COV-2. If not, please state so.' answered with 'NONE' (Site from Safety).	marsha gossett (b) (4) (b) (4)	14 Nov 2020 04:10:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:52

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'NO MEDICAL HX TO REPORT' (Site from Safety).	marsha gossett (b) (4)	14 Nov 2020 04:09:24
User opened query 'PV Query: Please clarify whether the subject had occupational/living and circumstances or occasions for exposure to SARS-COV-2. If not, please state so.' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:06:03
User opened query 'PV Query: Indication for Tylenol states Advil. Please clarify indication for Tylenol.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:05:33
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:05:18
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:05:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:25:55
User entered empty.	brittany cooksey (b) (4)	06 Nov 2020 17:42:56
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Nov 2020 17:42:56

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Nov 2020 17:42:56

US3302310

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:52

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	18 Jan 2021 19:30:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Jan 2021 19:30:15
Data point term sent to Coder	System	18 Jan 2021 19:29:00
User entered 'COVID-19'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered 'No (N)'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered 'No (N)'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered 'No (N)'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered '23 Nov 2020'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered empty.	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 19:28:41

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered 'No (N)'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered '23 Nov 2020'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered empty.	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 19:28:41

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered 'Grade 1/Mild (Grade 1/Mild)'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered 'No (N)'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered '0'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered '0'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered '0'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered empty.	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered empty.	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered empty.	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered empty.	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

US3302310

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered '0'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered '0'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered '0'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered 'Not Related (NOT RELATED)'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered 'Not Related (NOT RELATED)'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered 'Not Applicable (NOT APPLICABLE)'	brittany cooksey (b) (4) (b) (4)	18 Jan 2021 19:28:41

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered 'I'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered '0'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered '0'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:52

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

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered empty.	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 22:50:19
User entered empty.	brittany cooksey (b) (4)	18 Jan 2021 19:28:41
	(b) (4)	

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Jan 2021 19:28:41

**US3302310**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:22:52**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Jan 2021 19:28:41

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:22:52

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:13:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:03
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	20 Aug 2020 20:21:32

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:22:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:36:19
Un-reviewed for Data Management.	(b) (4), (b) (6)	07 Nov 2020 20:42:59
Reviewed for Data Management.	(b) (4), (b) (6)	07 Nov 2020 20:42:37
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: NORETHISTERONE, PRODUCTSYNONYM: MICRONOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 12:59:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 12:59:41
Data point term sent to Coder	System	20 Aug 2020 20:23:01
User entered 'micronor'	Brittany Belcher (b) (4)	20 Aug 2020 20:22:04

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:22:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 20:38:17
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'entry error' (Site from DM).	brittany cooksey (b) (4)	06 Nov 2020 17:32:19
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 17:32:14
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:16:47
User entered 'No (N)'	Brittany Belcher (b) (4)	20 Aug 2020 20:22:04

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'oral contraceptive'	Brittany Belcher (b) (4)	20 Aug 2020 20:22:04

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered '0.35'	Brittany Belcher (b) (4)	20 Aug 2020 20:22:04

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'mg (mg)'	Brittany Belcher (b) (4)	20 Aug 2020 20:22:04

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:22:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered empty.	Brittany Belcher (b) (4)	20 Aug 2020 20:22:04

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'once daily (QD)'	Brittany Belcher (b) (4)	20 Aug 2020 20:22:04

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:22:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered empty.	Brittany Belcher (b) (4)	20 Aug 2020 20:22:04

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	20 Aug 2020 20:22:04

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:52**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered empty.	Brittany Belcher (b) (4)	20 Aug 2020 20:22:04

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:22:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:36:19
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 06:02:07
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:28:52
User entered 'un Mar 2019'	Brittany Belcher (b) (4)	20 Aug 2020 20:22:04

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered '0'	Brittany Belcher (b) (4)	20 Aug 2020 20:22:04

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	20 Aug 2020 20:22:04

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered empty.	Brittany Belcher (b) (4)	20 Aug 2020 20:22:04

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'No (N)'	Brittany Belcher (b) (4)	20 Aug 2020 20:22:04

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:22:04

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:22:04

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:22:04

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:22:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Oct 2020 12:34:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Oct 2020 12:34:33
Data point term sent to Coder	System	22 Oct 2020 12:33:35
User entered 'Flu Vaccine'	Brittany Belcher (b) (4)	22 Oct 2020 12:33:27

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	22 Oct 2020 12:33:27

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'Vaccine'	Brittany Belcher (b) (4)	22 Oct 2020 12:33:27

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'l'	Brittany Belcher (b) (4)	22 Oct 2020 12:33:27

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:22:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'Other (OTHER)'	Brittany Belcher (b) (4)	22 Oct 2020 12:33:27

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:22:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'Injection'	Brittany Belcher (b) (4)	22 Oct 2020 12:33:27

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:22:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Un-verified.	(b) (4)	
	Brittany Belcher (b) (4)	26 Jan 2021 20:52:48
User entered 'once (ONCE)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	26 Jan 2021 20:52:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'other (OTHER)'	Brittany Belcher (b) (4)	22 Oct 2020 12:33:27

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:22:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
User closed query 'Per DM CLR: Please review "Other Frequency" as there is an available option for "Once" in the listed choices for frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 08:34:34
Query 'Per DM CLR: Please review "Other Frequency" as there is an available option for "Once" in the listed choices for frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' answered with 'updated.' (Site from DM).	Brittany Belcher (b) (4)	26 Jan 2021 20:53:05
DataPoint Un-verified.	Brittany Belcher (b) (4)	26 Jan 2021 20:52:48
User entered empty; reason for change Data Entry Error	Brittany Belcher (b) (4)	26 Jan 2021 20:52:48
User opened query 'Per DM CLR: Please review "Other Frequency" as there is an available option for "Once" in the listed choices for frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 09:17:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'One time dose'	Brittany Belcher (b) (4)	22 Oct 2020 12:33:27

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'Intramuscular (INTRAMUSCULAR)'	Brittany Belcher (b) (4)	22 Oct 2020 12:33:27

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:22:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered empty.	Brittany Belcher (b) (4)	22 Oct 2020 12:33:27

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered '10 Oct 2020'	Brittany Belcher (b) (4)	22 Oct 2020 12:33:27

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered '0'	Brittany Belcher (b) (4)	22 Oct 2020 12:33:27

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'No (N)'	Brittany Belcher (b) (4)	22 Oct 2020 12:33:27

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:52**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered '10 Oct 2020'	Brittany Belcher (b) (4)	22 Oct 2020 12:33:27

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:22:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:15
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 21:09:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 21:09:31
User entered 'No (N)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	22 Oct 2020 21:09:31
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 12:33:27
User entered empty.	Brittany Belcher (b) (4)	22 Oct 2020 12:33:27

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:15
User entered empty.	System	22 Oct 2020 12:33:27

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:15
User entered empty.	System	22 Oct 2020 12:33:27

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:15
User entered empty.	System	22 Oct 2020 12:33:27

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:22:52

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 22:15:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 22:15:54
Data point term sent to Coder	System	14 Nov 2020 04:12:40
Coding entries removed.	marsha gossett (b) (4)	14 Nov 2020 04:12:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:52:24
User closed query 'Please review source and revise if needed. Source states that name of medication is Advil.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:51:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 15:39:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 15:39:46
Data point term sent to Coder	System	10 Nov 2020 15:38:09
Query 'Please review source and revise if needed. Source states that name of medication is Advil.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	10 Nov 2020 15:37:16
Coding entries removed.	brittany cooksey (b) (4)	10 Nov 2020 15:37:10

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:22:52

Name of Medication

Audit	User	Time (GMT)
Coding entries removed.	brittany cooksey (b) (4)	10 Nov 2020 15:37:10
User entered 'Advil' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 15:37:10
User opened query 'Please review source and revise if needed. Source states that name of medication is Advil.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 02:38:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 02:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Nov 2020 17:38:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Nov 2020 17:38:21
Data point term sent to Coder	System	06 Nov 2020 17:37:30
Coding entries removed.	brittany cooksey (b) (4)	06 Nov 2020 17:37:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 19:32:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 19:32:32
Data point term sent to Coder	System	28 Oct 2020 17:15:24
User entered 'Tylenol'	Brittany Belcher (b) (4)	28 Oct 2020 17:15:03

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'No (N)'	Brittany Belcher (b) (4)	28 Oct 2020 17:15:03

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:22:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	24 Nov 2020 18:34:12
DataPoint Un-verified.	marsha gossett (b) (4)	14 Nov 2020 04:12:20
User entered 'HEADACHE (COVID SYMPTOM)' reason for change: Data Entry Error	marsha gossett (b) (4)	14 Nov 2020 04:12:20
User closed query 'Per DM CLR RQ: please clarify your response to previous query as response does not seem to address the query. Please, reconcile or update 'Name of Medication' and 'Indication' or clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 07:14:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:52:32
User closed query 'Please review source and revise if needed. Source states indication as "Headache". In addition, if headache was due to Covid, please make sure headache is in symptom log.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:52:15
Query 'Please review source and revise if needed. Source states indication as "Headache". In addition, if headache was due to Covid, please make sure headache is in symptom log.' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4)	10 Nov 2020 15:37:26
Query 'Per DM CLR RQ: please clarify your response to previous query as response does not seem to address the query. Please, reconcile or update 'Name of Medication' and 'Indication' or clarify.' answered with 'updated' (Site from DM).	brittany cooksey (b) (4)	10 Nov 2020 15:37:21
User entered 'headache' reason for change: Data Entry Error	brittany cooksey (b) (4)	10 Nov 2020 15:37:10
User opened query 'Please review source and revise if needed. Source states indication as "Headache". In addition, if headache was due to Covid, please make sure headache is in symptom log.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 02:41:47
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 02:38:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:22:52

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 20:47:32
User opened query 'Per DM CLR RQ: please clarify your response to previous query as response does not seem to address the query. Please, reconcile or update 'Name of Medication' and 'Indication' or clarify.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 20:47:30
Query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf. ' answered with 'Tylenol entered in error. however conmed log updated' (Site from DM).	brittany cooksey (b) (4)	06 Nov 2020 17:37:35
User entered 'advil' reason for change: Data Entry Error	brittany cooksey (b) (4)	06 Nov 2020 17:37:18
User opened query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:17:19
User entered 'injection pain'	Brittany Belcher (b) (4)	28 Oct 2020 17:15:03

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:22:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered '200' reason for change: Data Entry Error	brittany cooksey (b) (4)	06 Nov 2020 17:37:18
User entered '500'	Brittany Belcher (b) (4)	28 Oct 2020 17:15:03

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'mg (mg)'	Brittany Belcher (b) (4)	28 Oct 2020 17:15:03

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:52**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered empty.	Brittany Belcher (b) (4)	28 Oct 2020 17:15:03

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'as needed (PRN)'	Brittany Belcher (b) (4)	28 Oct 2020 17:15:03

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:22:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered empty.	Brittany Belcher (b) (4)	28 Oct 2020 17:15:03

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'Oral (ORAL)'	Brittany Belcher (b) (4)	28 Oct 2020 17:15:03

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:22:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered empty.	Brittany Belcher (b) (4)	28 Oct 2020 17:15:03

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:22:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered '01 Nov 2020' reason for change: Data Entry Error	brittany cooksey (b) (4)	06 Nov 2020 17:37:18
User entered '23 Aug 2020'	Brittany Belcher (b) (4)	28 Oct 2020 17:15:03

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered '0'	Brittany Belcher (b) (4)	28 Oct 2020 17:15:03

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:22:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:34:24
DataPoint Un-verified.	marsha gossett (b) (4)	14 Nov 2020 04:19:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	14 Nov 2020 04:19:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'Yes (Y)' reason for change: Data Entry Error	brittany cooksey (b) (4)	06 Nov 2020 17:37:18
User entered 'No (N)'	Brittany Belcher (b) (4)	28 Oct 2020 17:15:03

US3302310

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:22:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4)	24 Nov 2020 18:34:25
DataPoint Un-verified.	marsha gossett (b) (4)	14 Nov 2020 04:19:08
User entered '05 Nov 2020' reason for change: Data Entry Error	marsha gossett (b) (4)	14 Nov 2020 04:19:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered empty; reason for change Data Entry Error	brittany cooksey (b) (4)	06 Nov 2020 17:37:18
User entered '24 Aug 2020'	Brittany Belcher (b) (4)	28 Oct 2020 17:15:03

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:36:19
User entered 'No (N)'	Brittany Belcher (b) (4)	28 Oct 2020 17:15:03

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:19
User entered empty.	System	28 Oct 2020 17:15:03

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:19
User entered empty.	System	28 Oct 2020 17:15:03

**US3302310**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 22:51:19
User entered empty.	System	28 Oct 2020 17:15:03

US3302310

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:22:52

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
	(b) (4)	
User entered 'No (N)'	Brittany Belcher (b) (4)	20 Aug 2020 20:22:08

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered		
'USA-US087-2020-MRNA-1273-P301000004'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'Gregory'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'Feldman'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered '141 Harold Fleming Court'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'Spartanburg'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered '29303'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 23:59:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:34:08
User entered 'US'	System	09 Nov 2020 20:14:41

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
	(b) (4)	
User entered '2'	System	17 Nov 2020 00:00:07
User entered '1'	System	09 Nov 2020 20:14:41

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered		
'USA-US087-2020-MRNA-1273-P301000004'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'Gregory'	System	09 Nov 2020 20:13:52

US3302310

Folder: SAE USA-US087-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'Feldman'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered '141 Harold Fleming Court'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'Spartanburg'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered '29303'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 23:59:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:34:08
User entered 'US'	System	09 Nov 2020 20:14:41

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
	(b) (4)	
User entered '2'	System	17 Nov 2020 00:00:07
User entered '1'	System	09 Nov 2020 20:14:41

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (1)**

**Generated On: 11 Aug 2021 22:22:52**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 02:34:08
User entered '09/Nov/2020 20:14'	System	09 Nov 2020 20:14:41

US3302310

Folder: SAE USA-US087-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:22:52

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 23:59:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:34:08
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 20:14:41

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered		
'USA-US087-2020-MRNA-1273-P301000004'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'No (N)'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'Gregory'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'Feldman'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered '141 Harold Fleming Court'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered 'Spartanburg'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 02:34:08
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 20:14:21
User entered '29303'	System	09 Nov 2020 20:13:52

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 23:59:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:34:08
User entered 'US'	System	09 Nov 2020 20:14:41

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:52**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
User entered '2'	(b) (4)	17 Nov 2020 00:00:07
User entered '1'	System	09 Nov 2020 20:14:41

**US3302310**

**Folder: SAE USA-US087-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (2)**

**Generated On: 11 Aug 2021 22:22:52**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:32:16
User entered '17/Nov/2020 00:00'	System	17 Nov 2020 00:00:07

US3302310

Folder: SAE USA-US087-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:22:52

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 22:32:18
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 00:00:07