

US3082247 (Prod: Trial Management Associates LLC - ERN - PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:59:26

All time stamps listed in this document are displayed in GMT

US3082247

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 16:58:32

Generated On: 11 Aug 2021 21:59:26

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[Participant ID](#)

US3082247

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

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US3082247

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

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	SCRN

US3082247

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

Date of Birth (MMM yyyy)	(b) (6) 1979
Age	41
Age Units	YEARS
Age (Derived)	41
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

US3082247

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

Date of Informed Consent ( <i>dd MMM yyyy</i> )	16 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" 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

US3082247

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3082247

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

Were any significant conditions reported?

Yes ☐

No ☒

US3082247

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	16 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	08:30 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 08:30
Height ( <i>xxx.x</i> )	66.5 in
Weight ( <i>xxx.x</i> )	171 lb
BMI ( <i>xxx.x</i> )	27.24349 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3082247

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

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.*

US3082247

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

Date of assessment (dd MMM yyyy) 16 SEP 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

US3082247

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

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)	

US3082247

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

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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**

SUBJECT WORKS IN COVID-ICU  
AT HOSPITAL.

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

**No Risk Identified** True

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

US3082247

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

<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)	False
<b>Other</b>	False
<b>Specify</b>	

US3082247

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

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	VISIT1

US3082247

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

What was the date of randomization? (dd MMM yyyy) 16 SEP 2020

What was the participant's randomization number? 114275

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 ☒

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

Height	ND - Not Done
Weight	ND - Not Done

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

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)	16 SEP 2020
Time of assessment (00:00-23:59)	08:30 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 08:30
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

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)	16 SEP 2020
Time of assessment (00:00-23:59)	10:04 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 10:04
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)	56 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)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3082247

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

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.*

US3082247

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

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) \_\_\_\_\_

US3082247

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

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) 09:34 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 09:34

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

US3082247

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 SEP 2020

Collection time (00:00-23:59)

08:50 (24 HR)

Collection date and time (derived)

16 SEP 2020 08:50

US3082247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

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	08:45	16 SEP 2020 08:45
Nasopharyngeal Swab 2	No		

US3082247

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:59:26

**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

98.2 °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 10:04

PC Open Date & Time

16 SEP 2020 09:54

PC Close Date & Time

16 SEP 2020 12:24

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

**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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

16 SEP 2020 13:19

PC Close Date & Time

17 SEP 2020 11:59

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:59:26

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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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 13:51

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:59:26

**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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 13:23

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:59:26

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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 23:59

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:59:26

**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

98.2 °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

22 SEP 2020 00:22

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:59:26

---

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.9 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

22 SEP 2020 23:47

---

PC Open Date & Time

22 SEP 2020 12:00

---

PC Close Date & Time

23 SEP 2020 11:59

---

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 10:06

PC Open Date & Time

16 SEP 2020 09:54

PC Close Date & Time

16 SEP 2020 12:24

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

**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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the  
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE  
(in mm)**

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

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

PC Open Date & Time

16 SEP 2020 13:19

PC Close Date & Time

17 SEP 2020 11:59

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:59:26

**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 13:51

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:59:26

**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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the  
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE  
(in mm)**

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

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

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:59:26

**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 13:22

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:59:26

**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 23:59

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 00:22

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:59:26

**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 23:47

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:59:26

**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 ☐

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:59:26

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 10:06
PC Open Date & Time	16 SEP 2020 09:54
PC Close Date & Time	16 SEP 2020 12:24

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

**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 ☐

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

16 SEP 2020 13:19

PC Close Date & Time

17 SEP 2020 11:59

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:59:26

**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

EAB) (1725)

44 of 1658

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:59:26

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 13:52
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:59:26

**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  
EAB) (1725)

46 of 1658

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:59:26

Yes ☐

PC Time stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:59:26

**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 ☒

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:59:26

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 13:23
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:59:26

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 1658

EAB) (1725)

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:59:26

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

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:59:26

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 ☒

PRODUCTION RELEASE (v12.003

52 of 1658

EAB) (1725)

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:59:26

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 00:23
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:59:26

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 ☒

PRODUCTION RELEASE (v12.003

54 of 1658

EAB) (1725)

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:59:26

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 23:48
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3082247

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:58:33

Generated On: 11 Aug 2021 21:59:26

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*

US3082247

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:58:33

Generated On: 11 Aug 2021 21:59:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082247

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

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*

US3082247

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082247

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3082247

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082247

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT2

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3082247

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

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.*

US3082247

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

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) \_\_\_\_\_

US3082247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

Was study treatment given? Yes ☐  
No ☒

If No, reason not given

Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☒  
Other ☐

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

Which arm was used to give treatment? Left Arm ☐  
Right Arm ☐

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3082247

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3082247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

Collection date (*dd MMM yyyy*)

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

US3082247

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082247

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

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

PATIENT ON ILLNESS BLOCK  
DURING THIS TIME PERIOD

*If Contact Not Made, please provide Comments*

US3082247

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082247

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

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

PATIENT ON ILLNESS BLOCK  
DURING THIS TIME PERIOD

*If Contact Not Made, please provide Comments*

US3082247

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082247

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:58:33

Generated On: 11 Aug 2021 21:59:26

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

PATIENT ON ILLNESS BLOCK  
DURING THIS TIME PERIOD

*If Contact Not Made, please provide Comments*

US3082247

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:58:33

Generated On: 11 Aug 2021 21:59:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082247

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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	VISIT3

US3082247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 NOV 2020
Time of assessment (00:00-23:59)	09:35 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 09:35
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)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3082247

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

18 NOV 2020

---

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

---

US3082247

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 NOV 2020

Collection time (00:00-23:59)

09:50 (24 HR)

Collection date and time (derived)

18 NOV 2020 09:50

US3082247

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:32

Generated On: 11 Aug 2021 21:59:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

DAY 64

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

No ☒

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

19 NOV 2020 04:54:55

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

Please 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 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 NOV 2020 07:38:31
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 DEC 2020 15:23:34

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 00:39:49

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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	18 DEC 2020 07:18:14
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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 <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	28 DEC 2020 18:41:47
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

**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 JAN 2021 09:29:25

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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 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"/>

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

Please 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 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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	17 JAN 2021 12:10:30
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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 <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	25 JAN 2021 17:59:51
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

**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

01 FEB 2021 03:35:36

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

**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

08 FEB 2021 06:41:34

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

**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

12 FEB 2021 22:13:48

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

<b>TIMEPOINT</b>	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 <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 FEB 2021 07:56:14
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

<b>TIMEPOINT</b>	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 <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	01 MAR 2021 09:04:58
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

**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

05 MAR 2021 00:08:21

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

**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 ☒

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

12 MAR 2021 16:29:57

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3082247

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 21:59:26

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		01 MAR 2021 09:05:07

US3082247

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:58:33

Generated On: 11 Aug 2021 21:59:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

*If Contact Not Made, please provide Comments*

PT. DID NOT COMPLETE  
SAFETY CALL DESPITE  
MULTIPLE ATTEMPTS TO  
MAKE CONTACT. WILL  
FOLLOW UP AT NEXT PHONE  
CALL.

US3082247

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:58:33

Generated On: 11 Aug 2021 21:59:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082247

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:58:33

Generated On: 11 Aug 2021 21:59:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3082247

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:58:33

Generated On: 11 Aug 2021 21:59:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082247

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 12:34:34

Generated On: 11 Aug 2021 21:59:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

*If Contact Not Made, please provide Comments*

PARTICIPANT NEVER  
ANSWERED OUR TEXTS,  
CALLS, AND NEVER CALLED  
BACK

US3082247

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 12:34:34

Generated On: 11 Aug 2021 21:59:26

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Mar 2021 16:58:32

Generated On: 11 Aug 2021 21:59:26

Date of Contact	14 OCT 2020
Time of Contact	08:00
Date and Time of Contact (derived)	14 OCT 2020 08:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input checked="" 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>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

	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	15 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	101.1 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

111 of 1658

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

	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	16 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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 type="radio"/>
	Mild	<input checked="" 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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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 ☐

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

	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	17 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.4 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 type="radio"/>
	Mild	<input checked="" 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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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 ☐

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

	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	18 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.6 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 type="radio"/>
	Mild	<input checked="" 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)

123 of 1658

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

	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	19 OCT 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

	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	20 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.6 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 type="radio"/>
	Mild	<input checked="" 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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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 ☐

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

	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	21 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.4 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 type="radio"/>
	Mild	<input checked="" 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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

	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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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 ☐

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

	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	22 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.3 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)

139 of 1658

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

	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)

140 of 1658

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

	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	14 OCT 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

	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	13 OCT 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

	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	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

	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	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

	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	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

160 of 1658

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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"/>

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

	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	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

163 of 1658

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 22:02:50

Generated On: 11 Aug 2021 21:59:26

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

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Mar 2021 16:58:32

Generated On: 11 Aug 2021 21:59:26

Date of Visit 15 OCT 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Date of Test 15 OCT 2020

Type of Test Performed Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐ No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Mar 2021 16:58:32

Generated On: 11 Aug 2021 21:59:26

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 \_\_\_\_\_

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Mar 2021 16:58:32

Generated On: 11 Aug 2021 21:59:26

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

168 of 1658

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Mar 2021 16:58:32

Generated On: 11 Aug 2021 21:59:26

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

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 05 Mar 2021 16:58:32

Generated On: 11 Aug 2021 21:59:26

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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US3082247

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	Yes	11 NOV 2020

US3082247

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:58:33

Generated On: 11 Aug 2021 21:59:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD1

US3082247

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 16:58:33

Generated On: 11 Aug 2021 21:59:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	17:04 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 17:04
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" 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)	

US3082247

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 16:58:33

Generated On: 11 Aug 2021 21:59:26

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.*

US3082247

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 05 Mar 2021 16:58:33

Generated On: 11 Aug 2021 21:59:26

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

15 OCT 2020

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

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

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 NOV 2020
Time of assessment (00:00-23:59)	09:45 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 09:45
Height (xxx.x)	66.5 in
Weight (xxx.x)	171 lb
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 NOV 2020

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

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

11 NOV 2020

US3082247

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 12:34:34

Generated On: 11 Aug 2021 21:59:26

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

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

Folder OID UNBLND\_DECIDE

US3082247

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 12:34:34

Generated On: 11 Aug 2021 21:59:26

Date of updated informed consent (dd MMM yyyy) \_\_\_\_\_

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

Was the participant unblinded? Yes ☐  
No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐  
Amendment 6 or later ☐

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

Participant randomization assignment mRNA-1273 ☐  
Placebo ☐

Actual Dose 1 mRNA-1273 ☐  
Placebo ☐  
Not Administered ☐

Actual Dose 2 mRNA-1273 ☐  
Placebo ☐  
Not Administered ☐

Will participant receive mRNA-1273? Yes ☐  
No ☐

Placebo Only Flag \_\_\_\_\_

Continuing with mRNA-1273 \_\_\_\_\_

US3082247

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 12:34:34

Generated On: 11 Aug 2021 21:59:26

Was the sample collected? Yes ☐  
No ☐

Collection date (dd MMM yyyy) \_\_\_\_\_

Collection time (00:00-23:59) \_\_\_\_\_

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

US3082247

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 12:34:34

Generated On: 11 Aug 2021 21:59:26

Was the sample collected?

Yes ☐

No ☐

Collection date (dd MMM yyyy)

Collection time (00:00 - 23:59)

Collection Date and Time (derived)

US3082247

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3082247

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

AEID	USA-US114-2020-MRNA-1273-P30 1000005
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)	13 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)	22 OCT 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"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

185 of 1658

US3082247

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

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 checked="" type="radio"/> Not Applicable <input 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)	

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

---

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

Yes ☒

No ☐

---

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

---

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

Name of Medication NUVARING  
[ETONOGESTREL/ETHINYL  
ESTRADIOL]

Prophylaxis Yes ☒  
No ☐

Indication BIRTH CONTROL

Dose per administration 0.12/0.015

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

EVERY 3 WEEKS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

188 of 1658

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input checked="" type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
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"/>

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

190 of 1658

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
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"/>

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication COVID 19

Dose per administration 500

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

Q4HR ALTERNATING WITH  
IBUPROFEN

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

	Intraocular	<input type="checkbox"/>
	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)		14 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 OCT 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"/>

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication COVID 19

Dose per administration 400

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

Q4HR ALTERNATING WITH  
TYELNOL

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

194 of 1658

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

	Intraocular	<input type="checkbox"/>
	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)		14 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 OCT 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"/>

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

Name of Medication ZICAM [OXYMETAZOLINE  
HYDROCHLORIDE]

Prophylaxis Yes ☐  
No ☒

Indication COVID-19 SYMPTOM RELIEF

Dose per administration 1

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

196 of 1658

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

	Intraocular	<input type="checkbox"/>
	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)	16 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

Name of Medication VITAMIN C

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

198 of 1658

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

	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)	16 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication ANNUAL FLU PREVENTATIVE

Dose per administration 0.5

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

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

200 of 1658

EAB) (1725)

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 19:14:31

Generated On: 11 Aug 2021 21:59:26

	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)		29 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)		29 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"/>

US3082247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 16:58:32

Generated On: 11 Aug 2021 21:59:26

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Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3082247

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 16 Apr 2021 12:34:33

Generated On: 11 Aug 2021 21:59:26

Date of dosing discontinuation (dd MMM yyyy) 17 OCT 2020

Primary reason for dosing discontinuation

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

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

US3082247

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 16 Apr 2021 12:34:33

Generated On: 11 Aug 2021 21:59:26

Date of study discontinuation/completion (dd MMM yyyy) 15 MAR 2021

Reason for discontinuation

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

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

If reason for discontinuation is Death, main cause of death

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

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

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

US3082247

Folder: SAE USA-US114-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 05 Mar 2021 16:58:33

Generated On: 11 Aug 2021 21:59:26

SAEID	USA-US114-2020-MRNA-1273-P301000005
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	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3082247

Folder: SAE USA-US114-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Mar 2021 16:58:33

Generated On: 11 Aug 2021 21:59:26

SAEID	USA-US114-2020-MRNA-1273-P301000005
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	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/OCT/2020 16:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3082247

Folder: SAE USA-US114-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Mar 2021 16:58:33

Generated On: 11 Aug 2021 21:59:26

SAEID	USA-US114-2020-MRNA-1273-P301000005
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	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	21/OCT/2020 16:42
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

US3082247

Folder: SAE USA-US114-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Mar 2021 16:58:33

Generated On: 11 Aug 2021 21:59:26

SAEID	USA-US114-2020-MRNA-1273-P301000005
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	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/NOV/2020 20:25
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

US3082247

Folder: SAE USA-US114-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Mar 2021 16:58:33

Generated On: 11 Aug 2021 21:59:26

SAEID	USA-US114-2020-MRNA-1273-P301000005
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	BARTON
Investigator's Last Name	WILLIAMS
Site Address: Street	3806 PEACHTREE AVE.
Site Address: City	WILMINGTON
Site Address: State	NC
Site Address: Postal Code	28403
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/DEC/2020 06:55
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

US3082247 (Prod: Trial Management Associates LLC - ERN - PPDS)

**US3082247**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 21:59:26**

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:54:01
User entered 'US3082247'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Sep 2020 12:29:35

US3082247

Form: Participant Creation

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03

**US3082247**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:33
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:07:55

US3082247

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:33
User entered '16 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Sep 2020 12:29:36

US3082247

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:59:26

[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 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:33
User entered 'Clinic (Clinic)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:07:55

**US3082247**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'SCRN'	System	16 Sep 2020 13:07:55

US3082247

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:59:26

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:43
User entered (b) (6) 1979'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Sep 2020 12:29:37

**US3082247**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:59:26**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:43
User entered '41'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:08:12

**US3082247**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:59:26**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'YEARS'	System	16 Sep 2020 13:08:12

**US3082247**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:59:26**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered '41'	System	16 Sep 2020 13:08:48

**US3082247**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:59:26**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:43
User entered 'Female (F)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:08:12

US3082247

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:59:26

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:43
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:08:12

**US3082247**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:59:26**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:43
User entered 'I'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:08:12

**US3082247**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:59:26**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:43
User entered '0'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:08:12

**US3082247**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:59:26**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:43
User entered '0'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:08:12

**US3082247**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:59:26**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:43
User entered '0'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:08:12

**US3082247**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:59:26**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:43
User entered '0'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:08:12

US3082247

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:59:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:43
User entered '0'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:08:12

**US3082247**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:59:26**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:43
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:08:12

**US3082247**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:59:26**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:43
User entered '0'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:08:12

**US3082247**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:59:26**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:43
User entered '0'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:08:12

US3082247

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:59:26

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:57
User entered '16 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:08:48

**US3082247**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'Sep 2020'	System	16 Sep 2020 13:08:48

US3082247

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered '2020'	System	16 Sep 2020 13:08:48

**US3082247**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:59:26**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:57
User entered 'Amendment 3 (3)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:08:48

US3082247

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:57
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:08:48

**US3082247**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:59:26**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:57
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:08:48

**US3082247**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:59:26**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:57
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:08:48

**US3082247**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:59:26**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:57
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:08:48

US3082247

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:59:26

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:55:57
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Sep 2020 12:29:36

US3082247

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:59:26

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'I'	System	16 Sep 2020 13:09:06

US3082247

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:56:21
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:09:06

US3082247

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 21:59:26

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:56:35
Query 'Per CDM: It appears participant is 41 years of age, yet there are no Medical History or Concomitant Medications recorded. Please review, reconcile, and update ALL applicable forms accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 13:35:05
User opened query 'Per CDM: It appears participant is 41 years of age, yet there are no Medical History or Concomitant Medications recorded. Please review, reconcile, and update ALL applicable forms accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 20:03:25
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:09:19

US3082247

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:56:40
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:14:22

US3082247

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:56:40
User entered '16 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:14:22

**US3082247**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:56:40
User entered '08:30'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:14:22

**US3082247**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered '16 Sep 2020 08:30'	System	16 Sep 2020 13:14:22

US3082247

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:56:40
User entered '66.5' in	Erin Harrelson (b) (4)	16 Sep 2020 13:14:22
DataPoint set to visible.	(b) (4) System	16 Sep 2020 13:09:06

US3082247

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:56:40
User entered '171' lb	Erin Harrelson (b) (4)	16 Sep 2020 13:14:22
DataPoint set to visible.	(b) (4) System	16 Sep 2020 13:09:06

US3082247

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered '27.24349'	System	16 Sep 2020 13:14:22
DataPoint set to visible.	System	16 Sep 2020 13:09:06

US3082247

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'kg/m2'	System	16 Sep 2020 13:14:22
DataPoint set to visible.	System	16 Sep 2020 13:09:06

US3082247

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:56:40
User closed query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Height and Weight is recorded under screening Vital Signs eCRF. Please remove data for Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP and update to "ND- Not Done" . Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 14:50:56
Query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Height and Weight is recorded under screening Vital Signs eCRF. Please remove data for Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP and update to "ND- Not Done" . Thank you.' answered with 'DATA HAS BEEN CORRECTED' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 12:59:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 12:58:52
User opened query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Height and Weight is recorded under screening Vital Signs eCRF. Please remove data for Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP and update to "ND- Not Done" . Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 09:06:11
User entered '98.2' F	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:14:22

US3082247

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:40:36
User closed query 'Per CDM: When the Temperature is recorded as "ND", "Route of measurement" and "If Other, specify" fields should remain empty. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 09:38:00
Query 'Per CDM: When the Temperature is recorded as "ND", "Route of measurement" and "If Other, specify" fields should remain empty. Please update accordingly. ' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	15 Dec 2020 13:01:27
DataPoint Un-verified.	Erin Harrelson (b) (4) (b) (4)	15 Dec 2020 13:01:22
User entered empty; reason for change Data Entry Error	Erin Harrelson (b) (4) (b) (4)	15 Dec 2020 13:01:22
User opened query 'Per CDM: When the Temperature is recorded as "ND", "Route of measurement" and "If Other, specify" fields should remain empty. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 13:00:30
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 14:56:40
User entered 'Other (Other)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 12:58:52
User entered 'Oral (Oral)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:14:22

US3082247

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:40:36
DataPoint Un-verified.	Erin Harrelson (b) (4)	15 Dec 2020 13:01:22
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	15 Dec 2020 13:01:22
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 14:56:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Erin Harrelson (b) (4)	20 Oct 2020 12:58:52
User entered empty.	(b) (4) Erin Harrelson (b) (4)	16 Sep 2020 13:14:22

**US3082247**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:56:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 12:58:52
User entered '64'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:14:22

**US3082247**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'bpm'	System	16 Sep 2020 13:14:22

US3082247

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:56:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 12:58:52
User entered '14'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:14:22

US3082247

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'breaths/min'	System	16 Sep 2020 13:14:22

**US3082247**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:56:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 12:58:52
User entered '108'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:14:22

US3082247

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'mmHg'	System	16 Sep 2020 13:14:22

**US3082247**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:56:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 12:58:52
User entered '76'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:14:22

US3082247

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'mmHg'	System	16 Sep 2020 13:14:22

US3082247

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47

US3082247

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47

**US3082247**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:59:26**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:04
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:15:02

**US3082247**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:59:26**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:04
User entered '16 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:15:02

US3082247

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:59:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:12
User entered '16 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:15:45

US3082247

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:12
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:15:45

**US3082247**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:12
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:15:45

**US3082247**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:59:26**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:12
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:15:45

**US3082247**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:12
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:15:45

**US3082247**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:59:26**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:12
User entered '0'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:15:45

US3082247

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:12
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:15:45

**US3082247**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:59:26**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:12
User entered '0'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:15:45

**US3082247**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:59:26**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:20
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:18

**US3082247**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:59:26**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:20
User entered '16 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:18

**US3082247**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:59:26**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:20
User entered 'Urine (URINE)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:18

**US3082247**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:59:26**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:20
User entered 'Negative (NEGATIVE)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:18

**US3082247**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:59:26**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:20
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:18

**US3082247**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:59:26**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:20
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:18

**US3082247**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:59:26**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:20
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:18

**US3082247**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered empty.	System	16 Sep 2020 13:17:18

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:38
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:05

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:38
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:05

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:38
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:05

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:38
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:05

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:38
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:05

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:38
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:05

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:38
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:05

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:38
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:05

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:38
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:05

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:38
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:05

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:38
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:05

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:38
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:05

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:38
User entered 'Subject works in Covid-ICU at hospital.'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:05

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
User entered 'I'	(b) (4) Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:05

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:38
User entered '0'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:05

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:38
User entered '0'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:05

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:38
User entered '0'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:05

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:38
User entered '0'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:05

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:38
User entered '0'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:05

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
User entered '0'	Erin Harrelson (b) (4)	16 Sep 2020 13:17:05

US3082247

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:59:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:38
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:05

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:57
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:48

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:57
User entered '16 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:48

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

[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 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:57:57
User entered 'Clinic (Clinic)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:17:48

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'VISIT1'	System	16 Sep 2020 13:17:48

US3082247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:03
User entered '16 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Sep 2020 13:04:42

US3082247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:59:26

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:03
User entered '114275'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Sep 2020 13:04:42

US3082247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:03
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Sep 2020 13:04:42

US3082247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:03
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:20:13

US3082247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:03
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:20:13

US3082247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:03
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:20:13

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:03
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:20:13

US3082247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:59:26

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:03
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:20:13

US3082247

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:03
User entered 'No (N)'	Erin Harrelson (b) (4)	22 Sep 2020 19:29:31
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 09:19:08
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:19:07

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:59:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User closed query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on VID1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 14:51:01
Query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on VID1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you.' answered with 'DATA HAS BEEN CORRECTED' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 12:57:39
User entered missing code ND - Not Done; reason for change Data Entry Error	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 12:57:31
User opened query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on VID1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 09:07:44
User entered '66.5' in	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:59:26**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 12:57:31
User entered '171.0' lb	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:59:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User closed query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on VID1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 14:51:01
Query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on VID1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you.' answered with 'DATA HAS BEEN CORRECTED' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 12:57:39
User entered missing code ND - Not Done; reason for change Data Entry Error	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 12:57:31
User opened query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on VID1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 09:07:44
User entered '66.5' in	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:59:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 12:57:31
User entered '171.0' lb	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User accepted default value 'Pre-Dose (PREDOSE)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered '16 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered '08:30'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered '16 Sep 2020 08:30'	System	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered '98.2' F	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered 'Oral (Oral)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:59:26**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered '64'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'bpm'	System	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered '14'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'breaths/min'	System	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered '108'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'mmHg'	System	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered '76'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'mmHg'	System	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:59:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User closed query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on VID1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 14:51:01
Query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on VID1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you.' answered with 'DATA HAS BEEN CORRECTED' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 12:57:39
User entered missing code ND - Not Done; reason for change Data Entry Error	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 12:57:31
User opened query 'Per CDM: Per eCRF guidelines for subjects screened/randomized/dosed same day, only Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP has to be recorded on VID1 Vital Signs eCRF. Please remove data for weight and height and update to "ND- Not Done" . Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 09:07:44
User entered '66.5' in	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:59:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 12:57:31
User entered '171.0' lb	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User accepted default value 'Post-Dose (POSTDOSE)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered '16 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered '10:04'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered '16 Sep 2020 10:04'	System	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered '98.2' F	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:59:26**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered 'Oral (Oral)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered '56'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'bpm'	System	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered '14'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'breaths/min'	System	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered '118'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'mmHg'	System	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:23
User entered '76'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'mmHg'	System	16 Sep 2020 14:22:08

US3082247

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:59:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:33
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:20:43

US3082247

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:59:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:33
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:20:43

US3082247

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:59:26

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:42
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:20:49

US3082247

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:59:26

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:42
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:20:49

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:59:26**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:42
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:20:49

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:59:26**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:42
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:20:49

US3082247

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:59:26

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:42
User closed query 'Per CDM: Please record 'Was FSH sample collected as Yes or NO. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 14:52:03
Query 'Per CDM: Please record 'Was FSH sample collected as Yes or NO. Thank you.' answered with 'FSH SAMPLE NOT COLLECTED' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 12:50:41
User entered 'No (N)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 12:50:32
User opened query 'Per CDM: Please record 'Was FSH sample collected as Yes or NO. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 09:07:06
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:20:49

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:59:26**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:42
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:20:49

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:59:26**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:42
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:20:49

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered empty.	System	16 Sep 2020 13:20:49

US3082247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:59:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:49
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:44:44

US3082247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:59:26

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:44:44

US3082247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:59:26

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 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:44:44

US3082247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:59:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 13:44:44

US3082247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:59:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:49
User entered '16 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:44:44

US3082247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:49
User entered '09:34'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:44:44

US3082247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered '16 Sep 2020 09:34'	System	16 Sep 2020 13:44:44

US3082247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:58:49
User entered 'Left Arm (LEFT ARM)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:44:44

US3082247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 14:58:49
User entered 'ONCE'	System	16 Sep 2020 13:44:44

US3082247

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:59:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 13:44:44

US3082247

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:59:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:59:26
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:21:24

US3082247

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:59:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:59:26
User entered '16 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:21:24

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:59:26**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:59:26
User entered '08:50'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:21:24

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered '16 Sep 2020 08:50'	System	16 Sep 2020 13:21:24

US3082247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:59:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:59:36
User entered '16 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:21:49

US3082247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:59:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:21:49

US3082247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:59:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:59:36
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:21:49

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:59:36
User entered '08:45'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:21:49

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered '16 Sep 2020 08:45'	System	16 Sep 2020 13:21:49

US3082247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:59:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:21:49

US3082247

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:59:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:59:36
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:21:49

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:59:36
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:21:49

**US3082247**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered empty.	System	16 Sep 2020 13:21:49

US3082247

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:59:47
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:21:54

US3082247

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:59:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'I'	System	16 Sep 2020 13:21:54

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:59:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-16T10:04:06', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '6cb8a081-5d08-4e28-a461-ecb3d49d4327' User entered 'Yes (Y)'	System	16 Sep 2020 14:04:28
	System	16 Sep 2020 14:04:28

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:59:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-16T10:04:16', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '6cb8a081-5d08-4e28-a461-ecb3d49d4327' User entered '98.2'	System	16 Sep 2020 14:04:28
	System	16 Sep 2020 14:04:28

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-16T10:04:20', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '6cb8a081-5d08-4e28-a461-ecb3d49d4327'	System	16 Sep 2020 14:04:28
User entered 'No (N)'	System	16 Sep 2020 14:04:28

**US3082247**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-16T10:04:24', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '6cb8a081-5d08-4e28-a461-ecb3d49d4327' User entered '16 Sep 2020 10:04'	System	16 Sep 2020 14:04:28
	System	16 Sep 2020 14:04:28

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:59:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '16 Sep 2020 09:54'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:59:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '16 Sep 2020 12:24'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '16 Sep 2020 13:19'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 2'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:59:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-17T13:51:01', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '59e5321e-39ce-4137-a6a8-2e6cca0bc29a' User entered 'Yes (Y)'	System	17 Sep 2020 17:51:38
	System	17 Sep 2020 17:51:38

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:59:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-17T13:51:14', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '59e5321e-39ce-4137-a6a8-2e6cca0bc29a' User entered '98.0'	System	17 Sep 2020 17:51:38
	System	17 Sep 2020 17:51:38

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-17T13:51:17', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '59e5321e-39ce-4137-a6a8-2e6cca0bc29a' User entered 'No (N)'	System	17 Sep 2020 17:51:38
	System	17 Sep 2020 17:51:38

**US3082247**

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

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-17T13:51:20', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '59e5321e-39ce-4137-a6a8-2e6cca0bc29a' User entered '17 Sep 2020 13:51'	System	17 Sep 2020 17:51:38
	System	17 Sep 2020 17:51:38

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:59:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:59:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 3'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:59:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:59:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:59:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:59:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:59:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:59:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 4'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:59:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-19T13:23:02', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '5c4c3612-c914-4d05-b319-d3e9070ee2df' User entered 'Yes (Y)'	System	19 Sep 2020 17:23:15
	System	19 Sep 2020 17:23:15

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:59:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-19T13:23:07', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '5c4c3612-c914-4d05-b319-d3e9070ee2df' User entered '97.9'	System	19 Sep 2020 17:23:15
	System	19 Sep 2020 17:23:15

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-19T13:23:09', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '5c4c3612-c914-4d05-b319-d3e9070ee2df' User entered 'No (N)'	System	19 Sep 2020 17:23:15
	System	19 Sep 2020 17:23:15

**US3082247**

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

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

**Generated On: 11 Aug 2021 21:59:26**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-19T13:23:12', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '5c4c3612-c914-4d05-b319-d3e9070ee2df' User entered '19 Sep 2020 13:23'	System	19 Sep 2020 17:23:15
	System	19 Sep 2020 17:23:15

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:59:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:59:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 5'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:59:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-20T23:59:13', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '0325bdd3-cdc9-446c-951a-dc8421995178' User entered 'Yes (Y)'	System	21 Sep 2020 03:59:27
	System	21 Sep 2020 03:59:27

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:59:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-20T23:59:18', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '0325bdd3-cdc9-446c-951a-dc8421995178' User entered '98.1'	System	21 Sep 2020 03:59:27
	System	21 Sep 2020 03:59:27

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-20T23:59:21', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '0325bdd3-cdc9-446c-951a-dc8421995178' User entered 'No (N)'	System	21 Sep 2020 03:59:27
	System	21 Sep 2020 03:59:27

**US3082247**

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

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-20T23:59:24', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '0325bdd3-cdc9-446c-951a-dc8421995178' User entered '20 Sep 2020 23:59'	System	21 Sep 2020 03:59:27
	System	21 Sep 2020 03:59:27

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:59:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:59:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 6'	System	16 Sep 2020 13:44:44

**US3082247**

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

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:59:26**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T00:22:24', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '4b836f13-96ba-44a6-9bfa-516f50b75179' User entered 'Yes (Y)'	System	22 Sep 2020 04:22:36
	System	22 Sep 2020 04:22:36

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:59:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T00:22:29', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '4b836f13-96ba-44a6-9bfa-516f50b75179' User entered '98.2'	System	22 Sep 2020 04:22:36
	System	22 Sep 2020 04:22:36

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T00:22:31', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '4b836f13-96ba-44a6-9bfa-516f50b75179' User entered 'No (N)'	System	22 Sep 2020 04:22:36
	System	22 Sep 2020 04:22:36

**US3082247**

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

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T00:22:35', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '4b836f13-96ba-44a6-9bfa-516f50b75179' User entered '22 Sep 2020 00:22'	System	22 Sep 2020 04:22:36
	System	22 Sep 2020 04:22:36

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:59:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:59:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 7'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:59:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T23:47:25', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '1cdf4b81-099f-45bc-9178-804c549def1a' User entered 'Yes (Y)'	System	23 Sep 2020 03:47:37
	System	23 Sep 2020 03:47:37

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:59:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T23:47:29', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '1cdf4b81-099f-45bc-9178-804c549def1a' User entered '97.9'	System	23 Sep 2020 03:47:37
	System	23 Sep 2020 03:47:37

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T23:47:32', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '1cdf4b81-099f-45bc-9178-804c549def1a' User entered 'No (N)'	System	23 Sep 2020 03:47:37
	System	23 Sep 2020 03:47:37

**US3082247**

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

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

**Generated On: 11 Aug 2021 21:59:26**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T23:47:34', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '1cdf4b81-099f-45bc-9178-804c549def1a' User entered '22 Sep 2020 23:47'	System	23 Sep 2020 03:47:37
	System	23 Sep 2020 03:47:37

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:59:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:59:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:59:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-16T10:04:33', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'cae811af-fa98-48b1-94ef-df0e8f748d59'	System	16 Sep 2020 14:06:13
User entered 'None (1)'	System	16 Sep 2020 14:06:13

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:59:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-16T10:04:53', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'cae811af-fa98-48b1-94ef-df0e8f748d59'	System	16 Sep 2020 14:06:13
User entered 'No (N)'	System	16 Sep 2020 14:06:13

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-16T10:05:59', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'cae811af-fa98-48b1-94ef-df0e8f748d59'	System	16 Sep 2020 14:06:13
User entered 'No (N)'	System	16 Sep 2020 14:06:13

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:59:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-16T10:06:06', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'cae811af-fa98-48b1-94ef-df0e8f748d59'	System	16 Sep 2020 14:06:13
User entered 'None (1)'	System	16 Sep 2020 14:06:13

**US3082247**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-16T10:06:10', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'cae811af-fa98-48b1-94ef-df0e8f748d59'	System	16 Sep 2020 14:06:13
User entered '16 Sep 2020 10:06'	System	16 Sep 2020 14:06:13

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:59:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '16 Sep 2020 09:54'	System	16 Sep 2020 13:44:44

**US3082247**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '16 Sep 2020 12:24'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

**US3082247**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '16 Sep 2020 13:19'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 2'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:59:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-17T13:51:25', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '1a9c6f0c-48ae-4a2d-a05a-89c8f1744e5c'	System	17 Sep 2020 17:51:43
User entered 'None (1)'	System	17 Sep 2020 17:51:43

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:59:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-17T13:51:27', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '1a9c6f0c-48ae-4a2d-a05a-89c8f1744e5c' User entered 'No (N)'	System	17 Sep 2020 17:51:43
	System	17 Sep 2020 17:51:43

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-17T13:51:29', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '1a9c6f0c-48ae-4a2d-a05a-89c8f1744e5c' User entered 'No (N)'	System	17 Sep 2020 17:51:43
	System	17 Sep 2020 17:51:43

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:59:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-17T13:51:33', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '1a9c6f0c-48ae-4a2d-a05a-89c8f1744e5c' User entered 'None (1)'	System	17 Sep 2020 17:51:43
	System	17 Sep 2020 17:51:43

**US3082247**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-17T13:51:37', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '1a9c6f0c-48ae-4a2d-a05a-89c8f1744e5c' User entered '17 Sep 2020 13:51'	System	17 Sep 2020 17:51:43
	System	17 Sep 2020 17:51:43

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:59:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 13:44:44

**US3082247**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 3'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:59:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:59:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:59:26

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:59:26

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:59:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:59:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:59:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:59:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 4'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:59:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-19T13:22:41', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '7841f2d8-4775-4783-b0f8-d335a64a3269' User entered 'None (1)'	System	19 Sep 2020 17:22:56
	System	19 Sep 2020 17:22:56

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:59:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-19T13:22:44', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '7841f2d8-4775-4783-b0f8-d335a64a3269' User entered 'No (N)'	System	19 Sep 2020 17:22:56
	System	19 Sep 2020 17:22:56

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-19T13:22:47', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '7841f2d8-4775-4783-b0f8-d335a64a3269' User entered 'No (N)'	System	19 Sep 2020 17:22:56
	System	19 Sep 2020 17:22:56

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:59:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-19T13:22:48', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '7841f2d8-4775-4783-b0f8-d335a64a3269' User entered 'None (1)'	System	19 Sep 2020 17:22:56
	System	19 Sep 2020 17:22:56

**US3082247**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-19T13:22:55', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '7841f2d8-4775-4783-b0f8-d335a64a3269' User entered '19 Sep 2020 13:22'	System	19 Sep 2020 17:22:56
	System	19 Sep 2020 17:22:56

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:59:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 13:44:44

**US3082247**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 5'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:59:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-20T23:59:28', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '20a44679-f25e-46c8-8fc4-2b876c000064' User entered 'None (1)'	System	21 Sep 2020 03:59:40
	System	21 Sep 2020 03:59:40

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:59:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-20T23:59:31', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '20a44679-f25e-46c8-8fc4-2b876c000064' User entered 'No (N)'	System	21 Sep 2020 03:59:40
	System	21 Sep 2020 03:59:40

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-20T23:59:33', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '20a44679-f25e-46c8-8fc4-2b876c000064' User entered 'No (N)'	System	21 Sep 2020 03:59:40
	System	21 Sep 2020 03:59:40

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:59:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-20T23:59:35', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '20a44679-f25e-46c8-8fc4-2b876c000064' User entered 'None (1)'	System	21 Sep 2020 03:59:40
	System	21 Sep 2020 03:59:40

**US3082247**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-20T23:59:38', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '20a44679-f25e-46c8-8fc4-2b876c000064' User entered '20 Sep 2020 23:59'	System	21 Sep 2020 03:59:40
	System	21 Sep 2020 03:59:40

**US3082247**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 13:44:44

**US3082247**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 6'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:59:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T00:22:38', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'c79dd7f8-37ea-4b92-a99e-cad2b5413599'	System	22 Sep 2020 04:22:50
User entered 'None (1)'	System	22 Sep 2020 04:22:50

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:59:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T00:22:40', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'c79dd7f8-37ea-4b92-a99e-cad2b5413599'	System	22 Sep 2020 04:22:50
User entered 'No (N)'	System	22 Sep 2020 04:22:50

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T00:22:42', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'c79dd7f8-37ea-4b92-a99e-cad2b5413599' User entered 'No (N)'	System	22 Sep 2020 04:22:50
	System	22 Sep 2020 04:22:50

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:59:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T00:22:44', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'c79dd7f8-37ea-4b92-a99e-cad2b5413599'	System	22 Sep 2020 04:22:50
User entered 'None (1)'	System	22 Sep 2020 04:22:50

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:59:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T00:22:47', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'c79dd7f8-37ea-4b92-a99e-cad2b5413599' User entered '22 Sep 2020 00:22'	System	22 Sep 2020 04:22:50
	System	22 Sep 2020 04:22:50

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:59:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 13:44:44

**US3082247**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 7'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:59:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T23:47:38', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'daf1b881-f711-4ead-ba98-419d5336f8b6'	System	23 Sep 2020 03:47:49
User entered 'None (1)'	System	23 Sep 2020 03:47:49

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:59:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T23:47:40', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'daf1b881-f711-4ead-ba98-419d5336f8b6'	System	23 Sep 2020 03:47:49
User entered 'No (N)'	System	23 Sep 2020 03:47:49

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T23:47:42', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'daf1b881-f711-4ead-ba98-419d5336f8b6'	System	23 Sep 2020 03:47:49
User entered 'No (N)'	System	23 Sep 2020 03:47:49

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:59:26

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T23:47:43', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'daf1b881-f711-4ead-ba98-419d5336f8b6' User entered 'None (1)'	System	23 Sep 2020 03:47:49
	System	23 Sep 2020 03:47:49

**US3082247**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T23:47:46', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'daf1b881-f711-4ead-ba98-419d5336f8b6' User entered '22 Sep 2020 23:47'	System	23 Sep 2020 03:47:49
	System	23 Sep 2020 03:47:49

US3082247

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:59:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 13:44:44

**US3082247**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 13:44:44

**US3082247**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:59:26**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-16T10:06:16', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '9fe9a140-1f05-4ced-9a72-ea3ac5e6b715' User entered 'None (0)'	System	16 Sep 2020 14:06:46
	System	16 Sep 2020 14:06:46

**US3082247**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:59:26**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-16T10:06:23', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '9fe9a140-1f05-4ced-9a72-ea3ac5e6b715' User entered 'None (0)'	System	16 Sep 2020 14:06:46
	System	16 Sep 2020 14:06:46

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:59:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-16T10:06:26', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '9fe9a140-1f05-4ced-9a72-ea3ac5e6b715' User entered 'None (0)'	System	16 Sep 2020 14:06:46
	System	16 Sep 2020 14:06:46

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:59:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-16T10:06:28', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '9fe9a140-1f05-4ced-9a72-ea3ac5e6b715' User entered 'None (0)'	System	16 Sep 2020 14:06:46
	System	16 Sep 2020 14:06:46

**US3082247**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:59:26**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-16T10:06:31', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '9fe9a140-1f05-4ced-9a72-ea3ac5e6b715' User entered 'None (0)'	System	16 Sep 2020 14:06:46
	System	16 Sep 2020 14:06:46

**US3082247**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:59:26**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-16T10:06:34', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '9fe9a140-1f05-4ced-9a72-ea3ac5e6b715' User entered 'None (0)'	System	16 Sep 2020 14:06:46
	System	16 Sep 2020 14:06:46

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:59:26

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)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-16T10:06:38', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '9fe9a140-1f05-4ced-9a72-ea3ac5e6b715' User entered 'No (N)'	System	16 Sep 2020 14:06:46
	System	16 Sep 2020 14:06:46

**US3082247**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-16T10:06:42', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '9fe9a140-1f05-4ced-9a72-ea3ac5e6b715' User entered '16 Sep 2020 10:06'	System	16 Sep 2020 14:06:46
	System	16 Sep 2020 14:06:46

**US3082247**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '16 Sep 2020 09:54'	System	16 Sep 2020 13:44:44

**US3082247**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '16 Sep 2020 12:24'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

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)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '16 Sep 2020 13:19'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:59:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 2'	System	16 Sep 2020 13:44:44

**US3082247**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:59:26**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-17T13:51:42', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '6fd7ed9a-f69d-4917-ba66-7b5a13a81742' User entered 'None (0)'	System	17 Sep 2020 17:52:08
	System	17 Sep 2020 17:52:08

**US3082247**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:59:26**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-17T13:51:48', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '6fd7ed9a-f69d-4917-ba66-7b5a13a81742'	System	17 Sep 2020 17:52:08
User entered 'No interference with activity (1)'	System	17 Sep 2020 17:52:08

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:59:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-17T13:51:51', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '6fd7ed9a-f69d-4917-ba66-7b5a13a81742' User entered 'None (0)'	System	17 Sep 2020 17:52:08
	System	17 Sep 2020 17:52:08

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:59:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-17T13:51:53', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '6fd7ed9a-f69d-4917-ba66-7b5a13a81742' User entered 'None (0)'	System	17 Sep 2020 17:52:08
	System	17 Sep 2020 17:52:08

**US3082247**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:59:26**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-17T13:51:55', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '6fd7ed9a-f69d-4917-ba66-7b5a13a81742' User entered 'None (0)'	System	17 Sep 2020 17:52:08
	System	17 Sep 2020 17:52:08

**US3082247**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:59:26**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-17T13:51:58', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '6fd7ed9a-f69d-4917-ba66-7b5a13a81742' User entered 'None (0)'	System	17 Sep 2020 17:52:08
	System	17 Sep 2020 17:52:08

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:59:26

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)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-17T13:52:02', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '6fd7ed9a-f69d-4917-ba66-7b5a13a81742' User entered 'No (N)'	System	17 Sep 2020 17:52:08
	System	17 Sep 2020 17:52:08

**US3082247**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-17T13:52:05', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '6fd7ed9a-f69d-4917-ba66-7b5a13a81742' User entered '17 Sep 2020 13:52'	System	17 Sep 2020 17:52:08
	System	17 Sep 2020 17:52:08

**US3082247**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 13:44:44

**US3082247**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 3'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:59:26

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:59:26

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:59:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:59:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:59:26

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:59:26

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:59:26

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)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:59:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:59:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 13:44:44

**US3082247**

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

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

**Generated On: 11 Aug 2021 21:59:26**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 4'	System	16 Sep 2020 13:44:44

**US3082247**

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

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

**Generated On: 11 Aug 2021 21:59:26**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-19T13:23:16', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '261807a3-9b2c-4e3f-a3ca-6860632e0fc6' User entered 'None (0)'	System	19 Sep 2020 17:23:33
	System	19 Sep 2020 17:23:33

**US3082247**

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

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

**Generated On: 11 Aug 2021 21:59:26**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-19T13:23:17', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '261807a3-9b2c-4e3f-a3ca-6860632e0fc6' User entered 'None (0)'	System	19 Sep 2020 17:23:33
	System	19 Sep 2020 17:23:33

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:59:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-19T13:23:18', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '261807a3-9b2c-4e3f-a3ca-6860632e0fc6' User entered 'None (0)'	System	19 Sep 2020 17:23:33
	System	19 Sep 2020 17:23:33

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:59:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-19T13:23:20', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '261807a3-9b2c-4e3f-a3ca-6860632e0fc6' User entered 'None (0)'	System	19 Sep 2020 17:23:33
	System	19 Sep 2020 17:23:33

**US3082247**

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

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

**Generated On: 11 Aug 2021 21:59:26**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-19T13:23:21', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '261807a3-9b2c-4e3f-a3ca-6860632e0fc6' User entered 'None (0)'	System	19 Sep 2020 17:23:33
	System	19 Sep 2020 17:23:33

**US3082247**

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

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

**Generated On: 11 Aug 2021 21:59:26**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-19T13:23:22', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '261807a3-9b2c-4e3f-a3ca-6860632e0fc6' User entered 'None (0)'	System	19 Sep 2020 17:23:33
	System	19 Sep 2020 17:23:33

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:59:26

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)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-19T13:23:25', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '261807a3-9b2c-4e3f-a3ca-6860632e0fc6' User entered 'No (N)'	System	19 Sep 2020 17:23:33
	System	19 Sep 2020 17:23:33

**US3082247**

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

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

**Generated On: 11 Aug 2021 21:59:26**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-19T13:23:27', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '261807a3-9b2c-4e3f-a3ca-6860632e0fc6' User entered '19 Sep 2020 13:23'	System	19 Sep 2020 17:23:33
	System	19 Sep 2020 17:23:33

**US3082247**

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

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

**Generated On: 11 Aug 2021 21:59:26**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 13:44:44

**US3082247**

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

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

**Generated On: 11 Aug 2021 21:59:26**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:59:26

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 5'	System	16 Sep 2020 13:44:44

**US3082247**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:59:26**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-20T23:59:44', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '73c6f89b-bea8-460c-93e2-236938150c85' User entered 'None (0)'	System	21 Sep 2020 04:00:13
	System	21 Sep 2020 04:00:13

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:59:26

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-20T23:59:46', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '73c6f89b-bea8-460c-93e2-236938150c85' User entered 'None (0)'	System	21 Sep 2020 04:00:13
	System	21 Sep 2020 04:00:13

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:59:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-20T23:59:48', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '73c6f89b-bea8-460c-93e2-236938150c85' User entered 'None (0)'	System	21 Sep 2020 04:00:13
	System	21 Sep 2020 04:00:13

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:59:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-20T23:59:49', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '73c6f89b-bea8-460c-93e2-236938150c85' User entered 'None (0)'	System	21 Sep 2020 04:00:13
	System	21 Sep 2020 04:00:13

**US3082247**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:59:26**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-20T23:59:54', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '73c6f89b-bea8-460c-93e2-236938150c85' User entered 'None (0)'	System	21 Sep 2020 04:00:13
	System	21 Sep 2020 04:00:13

**US3082247**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:59:26**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-20T23:59:56', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '73c6f89b-bea8-460c-93e2-236938150c85' User entered 'None (0)'	System	21 Sep 2020 04:00:13
	System	21 Sep 2020 04:00:13

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:59:26

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)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-20T23:59:59', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '73c6f89b-bea8-460c-93e2-236938150c85' User entered 'No (N)'	System	21 Sep 2020 04:00:13
	System	21 Sep 2020 04:00:13

**US3082247**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-21T00:00:02', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '73c6f89b-bea8-460c-93e2-236938150c85' User entered '21 Sep 2020 00:00'	System	21 Sep 2020 04:00:13
	System	21 Sep 2020 04:00:13

**US3082247**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 13:44:44

**US3082247**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

**US3082247**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:59:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 6'	System	16 Sep 2020 13:44:44

**US3082247**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:59:26**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T00:23:01', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'a9dd6000-5564-4278-887b-8427339e1e86' User entered 'None (0)'	System	22 Sep 2020 04:23:16
	System	22 Sep 2020 04:23:16

**US3082247**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:59:26**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T00:23:02', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'a9dd6000-5564-4278-887b-8427339e1e86' User entered 'None (0)'	System	22 Sep 2020 04:23:16
	System	22 Sep 2020 04:23:16

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:59:26

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T00:23:04', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'a9dd6000-5564-4278-887b-8427339e1e86' User entered 'None (0)'	System	22 Sep 2020 04:23:16
	System	22 Sep 2020 04:23:16

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:59:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T00:23:05', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'a9dd6000-5564-4278-887b-8427339e1e86' User entered 'None (0)'	System	22 Sep 2020 04:23:16
	System	22 Sep 2020 04:23:16

**US3082247**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:59:26**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T00:23:07', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'a9dd6000-5564-4278-887b-8427339e1e86' User entered 'None (0)'	System	22 Sep 2020 04:23:16
	System	22 Sep 2020 04:23:16

**US3082247**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:59:26**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T00:23:08', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'a9dd6000-5564-4278-887b-8427339e1e86' User entered 'None (0)'	System	22 Sep 2020 04:23:16
	System	22 Sep 2020 04:23:16

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:59:26

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)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T00:23:10', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'a9dd6000-5564-4278-887b-8427339e1e86'	System	22 Sep 2020 04:23:16
User entered 'No (N)'	System	22 Sep 2020 04:23:16

**US3082247**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T00:23:12', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'a9dd6000-5564-4278-887b-8427339e1e86' User entered '22 Sep 2020 00:23'	System	22 Sep 2020 04:23:16
	System	22 Sep 2020 04:23:16

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:59:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 13:44:44

**US3082247**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:59:26**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

**US3082247**

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

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

**Generated On: 11 Aug 2021 21:59:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 7'	System	16 Sep 2020 13:44:44

**US3082247**

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

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

**Generated On: 11 Aug 2021 21:59:26**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T23:47:49', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '966a31ba-27cc-4616-8b49-cafa59e87ad3' User entered 'None (0)'	System	23 Sep 2020 03:48:02
	System	23 Sep 2020 03:48:02

**US3082247**

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

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

**Generated On: 11 Aug 2021 21:59:26**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T23:47:51', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '966a31ba-27cc-4616-8b49-cafa59e87ad3' User entered 'None (0)'	System	23 Sep 2020 03:48:02
	System	23 Sep 2020 03:48:02

**US3082247**

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

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

**Generated On: 11 Aug 2021 21:59:26**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T23:47:52', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '966a31ba-27cc-4616-8b49-cafa59e87ad3' User entered 'None (0)'	System	23 Sep 2020 03:48:02
	System	23 Sep 2020 03:48:02

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:59:26

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T23:47:54', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '966a31ba-27cc-4616-8b49-cafa59e87ad3' User entered 'None (0)'	System	23 Sep 2020 03:48:02
	System	23 Sep 2020 03:48:02

**US3082247**

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

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

**Generated On: 11 Aug 2021 21:59:26**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T23:47:55', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '966a31ba-27cc-4616-8b49-cafa59e87ad3' User entered 'None (0)'	System	23 Sep 2020 03:48:02
	System	23 Sep 2020 03:48:02

**US3082247**

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

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

**Generated On: 11 Aug 2021 21:59:26**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T23:47:56', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '966a31ba-27cc-4616-8b49-cafa59e87ad3' User entered 'None (0)'	System	23 Sep 2020 03:48:02
	System	23 Sep 2020 03:48:02

US3082247

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:59:26

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)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T23:47:58', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '966a31ba-27cc-4616-8b49-cafa59e87ad3' User entered 'No (N)'	System	23 Sep 2020 03:48:02
	System	23 Sep 2020 03:48:02

**US3082247**

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

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

**Generated On: 11 Aug 2021 21:59:26**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-09-22T23:48:00', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '966a31ba-27cc-4616-8b49-cafa59e87ad3' User entered '22 Sep 2020 23:48'	System	23 Sep 2020 03:48:02
	System	23 Sep 2020 03:48:02

**US3082247**

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

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

**Generated On: 11 Aug 2021 21:59:26**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 13:44:44

**US3082247**

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

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

**Generated On: 11 Aug 2021 21:59:26**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 13:44:44

**US3082247**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:59:26**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:59:57
User entered 'Yes (Y)'	Angie Northcott (b) (4) (b) (4)	23 Sep 2020 15:29:11

**US3082247**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:59:26**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:59:57
User entered '23 Sep 2020'	Angie Northcott (b) (4) (b) (4)	23 Sep 2020 15:29:11

US3082247

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:59:57
User entered 'Contact Made (CONTACT MADE)'	Angie Northcott (b) (4) (b) (4)	23 Sep 2020 15:29:11

**US3082247**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:59:26**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:59:57
User entered empty.	Angie Northcott (b) (4) (b) (4)	23 Sep 2020 15:29:11

US3082247

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:00:19
User entered 'Yes (Y)'	Angie Northcott (b) (4) (b) (4)	23 Sep 2020 15:29:16

US3082247

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:59:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'I'	System	23 Sep 2020 15:29:16

**US3082247**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:59:26**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:00:31
User entered 'Yes (Y)'	Ayssa Valente (b) (4) (b) (4)	30 Sep 2020 13:44:30

**US3082247**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:59:26**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:00:31
User entered '30 Sep 2020'	Ayssa Valente (b) (4) (b) (4)	30 Sep 2020 13:44:30

US3082247

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:00:31
User entered 'Contact Made (CONTACT MADE)'	Ayssa Valente (b) (4) (b) (4)	30 Sep 2020 13:44:30

**US3082247**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:59:26**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:00:31
User entered empty.	Ayssa Valente (b) (4) (b) (4)	30 Sep 2020 13:44:30

US3082247

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:00:39
User entered 'Yes (Y)'	Ayssa Valente (b) (4) (b) (4)	30 Sep 2020 13:44:34

**US3082247**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:59:26**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'I'	System	30 Sep 2020 13:44:34

**US3082247**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:59:26**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:00:49
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	08 Oct 2020 18:25:26

**US3082247**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:59:26**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:00:49
User entered '08 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	08 Oct 2020 18:25:26

US3082247

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:00:49
User entered 'Contact Made (CONTACT MADE)'	Erin Harrelson (b) (4) (b) (4)	08 Oct 2020 18:25:26

US3082247

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:00:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	08 Oct 2020 18:25:26

US3082247

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:09
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	08 Oct 2020 18:25:29

**US3082247**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:59:26**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:15:47
User entered 'I'	System	08 Oct 2020 18:25:29

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:25
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:15

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:25
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:15

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

[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 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:25
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:15

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User entered 'VISIT2'	System	09 Nov 2020 14:44:15

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User accepted default value 'Pre-Dose (PREDOSE)'	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:34
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:34
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:34
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User entered empty.	System	09 Nov 2020 14:44:24

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:34
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:34
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:59:26**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:34
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:34
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User entered empty.	System	09 Nov 2020 14:44:24

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:34
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User entered empty.	System	09 Nov 2020 14:44:24

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:34
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User entered empty.	System	09 Nov 2020 14:44:24

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:34
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:59:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User entered empty.	System	09 Nov 2020 14:44:24

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User accepted default value 'Post-Dose (POSTDOSE)'	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:34
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:34
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:34
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User entered empty.	System	09 Nov 2020 14:44:24

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:34
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:59:26**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:34
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:59:26**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:34
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:59:26**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:34
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:59:26**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User entered empty.	System	09 Nov 2020 14:44:24

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:34
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User entered empty.	System	09 Nov 2020 14:44:24

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:34
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User entered empty.	System	09 Nov 2020 14:44:24

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:34
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:24

US3082247

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:59:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User entered empty.	System	09 Nov 2020 14:44:24

US3082247

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:59:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:40
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 14:44:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 14:44:34
User entered 'No (N)' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:34
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 14:44:29
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:29

US3082247

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:59:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:40
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:29

US3082247

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:59:26

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:49
User closed query 'Per CDM: 'Is the participant of childbearing potential?' = Yes, however 'Was the pregnancy test performed?'= No. Please review, reconcile and update accordingly, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:33:06
Query 'Per CDM: 'Is the participant of childbearing potential?' = Yes, however 'Was the pregnancy test performed?'= No. Please review, reconcile and update accordingly, else clarify. Thank you. ' answered with 'The subject did not complete Visit 2 Day 29.' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	12 Nov 2020 12:53:40
User opened query 'Per CDM: 'Is the participant of childbearing potential?' = Yes, however 'Was the pregnancy test performed?'= No. Please review, reconcile and update accordingly, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 09:29:51
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:42

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:59:26**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:49
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:42

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:59:26**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:49
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:42

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:59:26**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:49
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:42

US3082247

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:59:26

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:49
User closed query 'Per CDM: Per CCGs, "Was FSH sample collected?" is to be answered and not left blank. Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 11:19:13
Query 'Per CDM: Per CCGs, "Was FSH sample collected?" is to be answered and not left blank. Please update as appropriate. ' answered with 'Answered' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	12 Nov 2020 17:34:23
User entered 'No (N)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	12 Nov 2020 17:34:14
User opened query 'Per CDM: Per CCGs, "Was FSH sample collected?" is to be answered and not left blank. Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:33:43
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:42

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:59:26**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:49
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:42

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:59:26**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:01:49
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:42

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User entered empty.	System	09 Nov 2020 14:44:42

US3082247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:59:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:01
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:57

US3082247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:59:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:01
User entered 'Confirmed COVID-19 (COVID)'	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:57

US3082247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:59:26

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 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:01
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:57

US3082247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:59:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User entered empty.	System	09 Nov 2020 14:44:57

US3082247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:59:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:01
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:57

US3082247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:01
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:57

US3082247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User entered empty.	System	09 Nov 2020 14:44:57

US3082247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:01
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:44:57

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 15:02:01
User entered empty.	System	09 Nov 2020 14:44:57

US3082247

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:59:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User entered empty.	System	09 Nov 2020 14:44:57

US3082247

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:59:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:10
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:45:03

US3082247

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:59:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:10
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:45:03

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:59:26**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:10
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:45:03

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User entered empty.	System	09 Nov 2020 14:45:03

US3082247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:59:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:15
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:45:10

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:45:10

US3082247

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:59:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:15
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:45:10

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:15
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:45:10

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User entered empty.	System	09 Nov 2020 14:45:10

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:59:26**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:45:10

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:59:26**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:15
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:45:10

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:59:26**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:15
User entered empty.	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:45:10

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User entered empty.	System	09 Nov 2020 14:45:10

US3082247

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:20
User entered 'Yes (Y)'	Morgan Mathis (b) (4) (b) (4)	09 Nov 2020 14:45:14

**US3082247**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:59:26**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:10:08
User entered '1'	System	09 Nov 2020 14:45:14

US3082247

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:20:14
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:32
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 15:17:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 15:17:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 15:17:22
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 15:15:12
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	18 Nov 2020 15:15:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 15:15:12
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	18 Nov 2020 15:09:25
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 15:09:25

US3082247

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:20:14
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:32
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Nov 2020 15:11:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 15:11:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Nov 2020 15:10:21
User entered 'UN UNK' (non-conformant).	(b) (4), (b) (6)	18 Nov 2020 15:10:21
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 15:09:25

US3082247

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:20:14
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:32
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 15:15:12
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	18 Nov 2020 15:09:25

US3082247

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:20:14
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:32
User entered 'PATIENT ON ILLNESS BLOCK DURING THIS TIME PERIOD' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 15:17:22
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 15:15:12
User entered 'ILLNESS BLOCK'	(b) (4), (b) (6)	18 Nov 2020 15:09:25

US3082247

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:20:14
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:38
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 15:17:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 15:17:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 15:17:42
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 15:15:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 15:15:33
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 15:11:58

**US3082247**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:59:26**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:20:14
User entered '1'	System	18 Nov 2020 15:17:42
User entered empty.	System	18 Nov 2020 15:11:58

US3082247

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:48
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	18 Nov 2020 20:48:13
Comment added 'Contact was not attempted or made because patient was on illness block during this time period. Therefore, patient was not contacted for Day 43 Safety Call'.	Morgan Mathis (b) (4) (b) (4)	18 Nov 2020 20:17:07
Comment added 'PATIENT ON ILLNESS BLOCK DURING THIS TIME PERIOD'.	(b) (4), (b) (6)	18 Nov 2020 15:20:20
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	18 Nov 2020 15:18:11
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 15:18:11

US3082247

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:48
User entered empty; reason for change Data Entry Error	Ayssa Valente (b) (4) (b) (4)	18 Nov 2020 20:48:13
User entered '21 Oct 2020' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	18 Nov 2020 20:46:34
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Nov 2020 15:20:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 15:20:02
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Nov 2020 15:19:45
User entered 'ND ND' (non-conformant).	(b) (4), (b) (6)	18 Nov 2020 15:19:45
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 15:18:11

US3082247

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:48
User entered empty; reason for change Data Entry Error	Ayssa Valente (b) (4)	18 Nov 2020 20:48:13
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	18 Nov 2020 15:18:11

US3082247

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:48
User entered 'PATIENT ON ILLNESS BLOCK DURING THIS TIME PERIOD'	(b) (4), (b) (6)	18 Nov 2020 15:18:11

**US3082247**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:02:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 15:19:10

**US3082247**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:59:26**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:58
User entered 'I'	System	18 Nov 2020 15:19:10

US3082247

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:02:00
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 15:03:03
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	18 Nov 2020 20:48:26
Comment added 'Contact was not attempted or made because patient was on illness block during this time period and therefore Day 50 safety call was not completed.'.	Morgan Mathis (b) (4)	18 Nov 2020 20:17:55
	(b) (4)	
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	18 Nov 2020 15:23:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 15:23:47

US3082247

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:02:00
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 15:03:03
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 15:23:47

US3082247

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:02:00
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 15:03:03
User entered empty; reason for change Data Entry Error	Ayssa Valente (b) (4)	18 Nov 2020 20:48:26
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	18 Nov 2020 15:23:47

US3082247

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:02:00
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 15:03:03
User entered 'PATIENT ON ILLNESS BLOCK DURING THIS TIME PERIOD'	(b) (4), (b) (6)	18 Nov 2020 15:23:47

US3082247

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:02:00
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 15:03:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 15:24:01

**US3082247**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:59:26**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:02:00
User entered '1'	System	18 Nov 2020 15:24:01

**US3082247**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:41:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 15:24:16

US3082247

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:59:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:41:28
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	14 Dec 2020 20:14:17
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	14 Dec 2020 19:50:20
User entered '18 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 15:24:16

US3082247

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:59:26

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 05:16:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:41:28
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	18 Nov 2020 15:24:21
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 15:24:21
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	18 Nov 2020 15:24:16
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 15:24:16

**US3082247**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User entered 'VISIT3'	System	18 Nov 2020 15:24:16

US3082247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:41:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 15:25:21

US3082247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:41:36
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 20:14:17
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 19:50:20
User entered '18 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 15:25:21

**US3082247**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:41:36
User entered '09:35'	(b) (4), (b) (6)	18 Nov 2020 15:25:21

**US3082247**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User entered '18 Nov 2020 09:35'	System	18 Nov 2020 15:25:21

US3082247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:41:36
User entered '97.5' F	(b) (4), (b) (6)	18 Nov 2020 15:25:21

**US3082247**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:41:36
User entered 'Oral (Oral)'	(b) (4), (b) (6)	18 Nov 2020 15:25:21

**US3082247**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:41:36
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 15:25:21

US3082247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:41:36
User entered '71'	(b) (4), (b) (6)	18 Nov 2020 15:25:21

**US3082247**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User entered 'bpm'	System	18 Nov 2020 15:25:21

US3082247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:41:36
User entered '18'	(b) (4), (b) (6)	18 Nov 2020 15:25:21

US3082247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User entered 'breaths/min'	System	18 Nov 2020 15:25:21

US3082247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:41:36
User entered '118'	(b) (4), (b) (6)	18 Nov 2020 15:25:21

**US3082247**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User entered 'mmHg'	System	18 Nov 2020 15:25:21

US3082247

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:41:36
User entered '88'	(b) (4), (b) (6)	18 Nov 2020 15:25:21

**US3082247**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User entered 'mmHg'	System	18 Nov 2020 15:25:21

**US3082247**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48

**US3082247**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48

US3082247

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:59:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:41:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 15:25:35

US3082247

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:59:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:41:52
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	14 Dec 2020 20:14:17
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	14 Dec 2020 20:11:23
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	14 Dec 2020 20:11:23
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	14 Dec 2020 20:11:23
User entered '18 Nov 2020' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	14 Dec 2020 20:11:23
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	14 Dec 2020 20:09:14
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	14 Dec 2020 20:09:14
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	14 Dec 2020 20:09:14
User entered '11 Nov 2020' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	14 Dec 2020 20:09:14
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	14 Dec 2020 19:50:20
User entered '18 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 15:25:35

**US3082247**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:59:26**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:41:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 15:25:56

US3082247

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:59:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:41:58
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	14 Dec 2020 20:14:17
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	14 Dec 2020 19:50:20
User entered '18 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 15:25:56

**US3082247**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:59:26**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:41:58
User entered '09:50'	(b) (4), (b) (6)	18 Nov 2020 15:25:56

**US3082247**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User entered '18 Nov 2020 09:50'	System	18 Nov 2020 15:25:56

US3082247

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:42:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 15:26:00

**US3082247**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:59:26**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:16:48
User entered '1'	System	18 Nov 2020 15:26:00

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered 'Day 64'	System	16 Sep 2020 13:44:44

US3082247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

[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)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-11-19T04:54:45', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '68c6e1fa-2c66-4c6a-8163-5bae9c1235bf' User entered 'No (N)'	System	19 Nov 2020 09:55:02
	System	19 Nov 2020 09:55:02

US3082247

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-11-19T04:54:50', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '68c6e1fa-2c66-4c6a-8163-5bae9c1235bf'	System	19 Nov 2020 09:55:02
User entered 'No (N)'	System	19 Nov 2020 09:55:02

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-11-19T04:54:55', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '68c6e1fa-2c66-4c6a-8163-5bae9c1235bf' User entered '19 Nov 2020 04:54:55'	System	19 Nov 2020 09:55:02
	System	19 Nov 2020 09:55:02

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered '16 Nov 2020 00:01'	System	16 Sep 2020 13:44:44

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 11:13:03
Data entry locked.	System	16 Sep 2020 13:44:44
User entered '20 Nov 2020 23:59'	System	16 Sep 2020 13:44:44

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 08:50:49

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

[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)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Please 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)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Please 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)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

US3082247

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Please 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)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:50:49

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

[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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-11-27T07:38:25', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '1db25ff1-54ce-4fb3-8a18-757641075caf' User entered 'No (N)'	System	27 Nov 2020 12:38:33
	System	27 Nov 2020 12:38:33

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-11-27T07:38:28', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '1db25ff1-54ce-4fb3-8a18-757641075caf'	System	27 Nov 2020 12:38:33
User entered 'No (N)'	System	27 Nov 2020 12:38:33

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-11-27T07:38:31', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'ldb25ff1-54ce-4fb3-8a18-757641075caf' User entered '27 Nov 2020 07:38:31'	System	27 Nov 2020 12:38:33
	System	27 Nov 2020 12:38:33

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:50:49

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-12-08T15:23:26', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '0b4fb0c0-4955-4bb4-973b-0da8eaa6f63c' User entered 'No (N)'	System	08 Dec 2020 20:23:40
	System	08 Dec 2020 20:23:40

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-12-08T15:23:30', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '0b4fb0c0-4955-4bb4-973b-0da8eaa6f63c' User entered 'No (N)'	System	08 Dec 2020 20:23:40
	System	08 Dec 2020 20:23:40

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-12-08T15:23:34', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '0b4fb0c0-4955-4bb4-973b-0da8eaa6f63c' User entered '08 Dec 2020 15:23:34'	System	08 Dec 2020 20:23:40
	System	08 Dec 2020 20:23:40

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-12-12T00:39:40', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '500e087d-ea32-4265-85cd-a549cf6a9883'	System	12 Dec 2020 05:45:16
User entered 'No (N)'	System	12 Dec 2020 05:45:16

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-12-12T00:39:46', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '500e087d-ea32-4265-85cd-a549cf6a9883'	System	12 Dec 2020 05:45:16
User entered 'No (N)'	System	12 Dec 2020 05:45:16

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-12-12T00:39:49', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '500e087d-ea32-4265-85cd-a549cf6a9883' User entered '12 Dec 2020 00:39:49'	System	12 Dec 2020 05:45:16
	System	12 Dec 2020 05:45:16

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:50:49

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

[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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-12-18T07:18:06', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'f5a3bf9b-66c8-4b61-a2f2-40188e7d16ff'	System	18 Dec 2020 12:18:19
User entered 'No (N)'	System	18 Dec 2020 12:18:19
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-12-18T07:18:11', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'f5a3bf9b-66c8-4b61-a2f2-40188e7d16ff'	System	18 Dec 2020 12:18:19
User entered 'No (N)'	System	18 Dec 2020 12:18:19
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-12-18T07:18:14', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'f5a3bf9b-66c8-4b61-a2f2-40188e7d16ff'	System	18 Dec 2020 12:18:19
User entered '18 Dec 2020 07:18:14'	System	18 Dec 2020 12:18:19
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:50:49

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

[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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-12-28T18:40:53', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '36159a51-c55a-4e69-9640-fd124fe58139'	System	28 Dec 2020 23:41:59
User entered 'No (N)'	System	28 Dec 2020 23:41:59
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-12-28T18:41:42', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '36159a51-c55a-4e69-9640-fd124fe58139'	System	28 Dec 2020 23:41:59
User entered 'Yes (Y)'	System	28 Dec 2020 23:41:59
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

Please 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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-12-28T18:41:27', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '36159a51-c55a-4e69-9640-fd124fe58139'	System	28 Dec 2020 23:41:59
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Dec 2020 23:41:59
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2020-12-28T18:41:47', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '36159a51-c55a-4e69-9640-fd124fe58139'	System	28 Dec 2020 23:41:59
User entered '28 Dec 2020 18:41:47'	System	28 Dec 2020 23:41:59
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:50:49

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

[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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-01-05T09:29:19', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '442e3be7-3298-4201-952d-ad117e1a7d34'	System	05 Jan 2021 14:29:28
User entered 'No (N)'	System	05 Jan 2021 14:29:28
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-01-05T09:29:21', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '442e3be7-3298-4201-952d-ad117e1a7d34'	System	05 Jan 2021 14:29:28
User entered 'No (N)'	System	05 Jan 2021 14:29:28
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-01-05T09:29:25', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '442e3be7-3298-4201-952d-ad117e1a7d34'	System	05 Jan 2021 14:29:28
User entered '05 Jan 2021 09:29:25'	System	05 Jan 2021 14:29:28
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:50:49

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

[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)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Please 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)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Please 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)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Please 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)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:50:49

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

[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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-01-17T12:10:24', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'be90e867-5cea-4ef9-a3ca-8fbdb89e0f67'	System	17 Jan 2021 17:10:34
User entered 'No (N)'	System	17 Jan 2021 17:10:34
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-01-17T12:10:26', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'be90e867-5cea-4ef9-a3ca-8fbd89e0f67'	System	17 Jan 2021 17:10:34
User entered 'No (N)'	System	17 Jan 2021 17:10:34
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-01-17T12:10:30', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'be90e867-5cea-4ef9-a3ca-8fbdb89e0f67'	System	17 Jan 2021 17:10:34
User entered '17 Jan 2021 12:10:30'	System	17 Jan 2021 17:10:34
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

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**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:50:49

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-01-25T17:59:47', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '2fc36125-25a1-4e49-a513-9eb6329cf13b'	System	25 Jan 2021 22:59:56
User entered 'No (N)'	System	25 Jan 2021 22:59:56
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-01-25T17:59:48', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '2fc36125-25a1-4e49-a513-9eb6329cf13b'	System	25 Jan 2021 22:59:56
User entered 'No (N)'	System	25 Jan 2021 22:59:56
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-01-25T17:59:51', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '2fc36125-25a1-4e49-a513-9eb6329cf13b'	System	25 Jan 2021 22:59:56
User entered '25 Jan 2021 17:59:51'	System	25 Jan 2021 22:59:56
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:50:49

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

[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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-02-01T03:35:31', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'd34b81e1-01ef-45d0-8d75-a4ac0775504d'	System	01 Feb 2021 08:35:38
User entered 'No (N)'	System	01 Feb 2021 08:35:38
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-02-01T03:35:32', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'd34b81e1-01ef-45d0-8d75-a4ac0775504d'	System	01 Feb 2021 08:35:38
User entered 'No (N)'	System	01 Feb 2021 08:35:38
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-02-01T03:35:36', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'd34b81e1-01ef-45d0-8d75-a4ac0775504d' User entered '01 Feb 2021 03:35:36'	System	01 Feb 2021 08:35:38
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:50:49

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-02-08T06:41:29', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '45e7acf2-b517-4c50-a247-c1da59ebbc74'	System	08 Feb 2021 11:41:37
User entered 'No (N)'	System	08 Feb 2021 11:41:37
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-02-08T06:41:30', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '45e7acf2-b517-4c50-a247-c1da59ebbc74'	System	08 Feb 2021 11:41:37
User entered 'No (N)'	System	08 Feb 2021 11:41:37
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-02-08T06:41:34', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '45e7acf2-b517-4c50-a247-c1da59ebbc74'	System	08 Feb 2021 11:41:37
User entered '08 Feb 2021 06:41:34'	System	08 Feb 2021 11:41:37
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:50:49

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

[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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-02-12T22:13:44', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'f930cc1c-bdd9-4276-8e93-500174e2e110'	System	13 Feb 2021 03:13:57
User entered 'No (N)'	System	13 Feb 2021 03:13:57
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-02-12T22:13:45', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'f930cc1c-bdd9-4276-8e93-500174e2e110'	System	13 Feb 2021 03:13:57
User entered 'No (N)'	System	13 Feb 2021 03:13:57
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

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**Generated On: 11 Aug 2021 21:59:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-02-12T22:13:48', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'f930cc1c-bdd9-4276-8e93-500174e2e110'	System	13 Feb 2021 03:13:57
User entered '12 Feb 2021 22:13:48'	System	13 Feb 2021 03:13:57
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:50:49

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

[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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-02-19T07:55:29', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '91eac6b3-35cf-45f0-bfbe-5f13ee62b4f1'	System	01 Mar 2021 09:04:49
User entered 'No (N)'	System	01 Mar 2021 09:04:49
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-02-19T07:55:34', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '91eac6b3-35cf-45f0-bfbe-5f13ee62b4f1'	System	01 Mar 2021 09:04:49
User entered 'No (N)'	System	01 Mar 2021 09:04:49
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-02-19T07:56:14', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '91eac6b3-35cf-45f0-bfbc-5f13ee62b4f1' User entered '19 Feb 2021 07:56:14'	System	01 Mar 2021 09:04:49
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

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**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:50:49

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

[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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-03-01T04:04:54-05:00', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '9021e777-b9f8-4c5f-89aa-caab1e7b7352'	System	01 Mar 2021 09:05:02
User entered 'No (N)'	System	01 Mar 2021 09:05:02
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-03-01T04:04:55-05:00', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '9021e777-b9f8-4c5f-89aa-caab1e7b7352'	System	01 Mar 2021 09:05:02
User entered 'No (N)'	System	01 Mar 2021 09:05:02
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-03-01T04:04:58-05:00', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '9021e777-b9f8-4c5f-89aa-caab1e7b7352'	System	01 Mar 2021 09:05:02
User entered '01 Mar 2021 09:04:58'	System	01 Mar 2021 09:05:02
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:50:49

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

[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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-03-05T00:08:04-05:00', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '77554f5a-ef55-40f8-9823-767e4dea7723'	System	05 Mar 2021 05:08:23
User entered 'No (N)'	System	05 Mar 2021 05:08:23
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-03-05T00:08:06-05:00', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '77554f5a-ef55-40f8-9823-767e4dea7723'	System	05 Mar 2021 05:08:23
User entered 'No (N)'	System	05 Mar 2021 05:08:23
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-03-05T00:08:21-05:00', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: '77554f5a-ef55-40f8-9823-767e4dea7723'	System	05 Mar 2021 05:08:23
User entered '05 Mar 2021 00:08:21'	System	05 Mar 2021 05:08:23
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:50:49

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

[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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-03-12T16:29:52-05:00', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'dd2c6dcd-9af7-4a40-b121-e2fa3457ee35'	System	12 Mar 2021 21:29:59
User entered 'No (N)'	System	12 Mar 2021 21:29:59
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

US3082247

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:59:26

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)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-03-12T16:29:53-05:00', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'dd2c6dcd-9af7-4a40-b121-e2fa3457ee35'	System	12 Mar 2021 21:29:59
User entered 'No (N)'	System	12 Mar 2021 21:29:59
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-03-12T16:29:57-05:00', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'dd2c6dcd-9af7-4a40-b121-e2fa3457ee35'	System	12 Mar 2021 21:29:59
User entered '12 Mar 2021 16:29:57'	System	12 Mar 2021 21:29:59
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 08:50:49

**US3082247**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:59:26**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Activated.	System	14 Dec 2020 20:14:17
DataPoint Inactivated.	System	14 Dec 2020 19:50:20
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:50:49
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 08:50:49

US3082247

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:59:26

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)	30 Apr 2021 07:21:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-03-01T04:05:04-05:00', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'e036e54e-a493-4a3a-be03-2843827fd2cf' User entered 'No (N)'	System	01 Mar 2021 09:05:11
	System	01 Mar 2021 09:05:11

**US3082247**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:21:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C83C4903-F664-4EDE-A5EA-6133546502E9)', Time: '2021-03-01T04:05:07-05:00', User OID: 'PatientReportedOutcome (US3082247)', ODM File OID: 'e036e54e-a493-4a3a-be03-2843827fd2cf' User entered '01 Mar 2021 09:05:07'	System	01 Mar 2021 09:05:11
	System	01 Mar 2021 09:05:11

**US3082247**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:59:26**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:15:06
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:43:05
User entered 'Yes (Y)'	Alice Cipollini (b) (4) (b) (4)	14 Dec 2020 19:22:41

US3082247

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:15:06
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:43:05
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 20:14:17
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 19:50:20
User entered '14 Dec 2020'	Alice Cipollini (b) (4) (b) (4)	14 Dec 2020 19:22:41

US3082247

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:15:06
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:43:05
User entered 'Contact Not Made (CONTACT NOT MADE)'	Alice Cipollini (b) (4) (b) (4)	14 Dec 2020 19:22:41

US3082247

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:15:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:16:18
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	(b) (4)	19 Jan 2021 16:45:40
Please review and reconcile.' (Site from System).		
User entered 'Pt. did not complete safety call despite multiple attempts to make contact. Will follow up at next phone call.' reason for change: Data Entry Error	Erin Harrelson (b) (4)	19 Jan 2021 16:45:40
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	19 Jan 2021 16:44:18
Please review and reconcile.' (Site from System).		
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Jan 2021 16:44:18
User entered empty; reason for change Data Entry Error	(b) (4)	
	Erin Harrelson (b) (4)	19 Jan 2021 16:44:18
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 15:43:05
User entered 'Patient was discontinued from the study, due to testing positive for COVID 19.'	Alice Cipollini (b) (4)	14 Dec 2020 19:22:41
	(b) (4)	

US3082247

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:15:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:28:29
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Un-verified.	(b) (4)	
	Erin Harrelson (b) (4)	19 Jan 2021 16:43:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Erin Harrelson (b) (4)	19 Jan 2021 16:43:36
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 15:44:23
User entered 'No (N)'	Alice Cipollini (b) (4)	14 Dec 2020 19:22:47
	(b) (4)	

**US3082247**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:59:26**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:15:06
User entered 'I'	System	19 Jan 2021 16:43:36
User entered empty.	System	14 Dec 2020 19:22:47

**US3082247**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:59:26**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:44:20
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:23:01
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered 'Yes (Y)'	(b) (4) Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 16:48:46

**US3082247**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:59:26**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:44:20
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:23:01
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered '19 Jan 2021'	(b) (4) Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 16:48:46

US3082247

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:44:20
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:23:01
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 16:48:46

**US3082247**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:59:26**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:44:20
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:23:01
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 16:48:46

US3082247

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:44:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:58:34
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered 'Yes (Y)'	(b) (4) Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 16:48:53

**US3082247**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:59:26**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:44:20
User entered 'I'	System	19 Jan 2021 16:48:53

US3082247

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:59:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:19:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:46:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	30 Mar 2021 19:12:42
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	30 Mar 2021 19:10:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 19:10:26

**US3082247**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:59:26**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:19:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:46:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User entered '11 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 19:12:42
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:10:26

**US3082247**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:19:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:46:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:10:26

**US3082247**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:59:26**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:19:36
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:46:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User entered 'Participant never answered our texts, calls, and never called back'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:10:26

**US3082247**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:19:36
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:58:54
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 19:13:03

**US3082247**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:59:26**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:19:36
User entered empty.	System	30 Mar 2021 19:13:03

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:59:26

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:00:55
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User closed query ' Per CDM: It appears that both initial start date of symptoms and contact date are the same (15OCT2020). Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:17:22
Query ' Per CDM: It appears that both initial start date of symptoms and contact date are the same (15OCT2020). Please review and reconcile.' answered with 'date corrected' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:01
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:57:36
User entered '14 Oct 2020' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:57:36
User opened query ' Per CDM: It appears that both initial start date of symptoms and contact date are the same (15OCT2020). Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 03:02:15
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:21:24
User entered '15 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:37:38

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:59:26

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:21:24
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 12:38:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 12:38:16
User entered '08:00' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:38:16
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 12:37:38
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:37:38

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:59:26

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User entered '14 Oct 2020 08:00'	System	08 Jan 2021 12:57:36
User entered '15 Oct 2020 08:00'	System	16 Oct 2020 12:38:16
User entered empty.	System	16 Oct 2020 12:37:38

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:59:26

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:21:24
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)' reason for change: Data Entry Error	Flo Abbott (b) (4)	19 Oct 2020 17:01:54
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:37:38

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:59:26

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:21:24
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:37:38

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	08 Jan 2021 12:59:13
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
User entered 'Day 1 (Day 1)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
User closed query 'Per ETRTR: Upon onset of Symptoms that triggered Illness visit, please update AE CRF page "Start date" data point with the day when subject started COVID symptoms, thanks.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 04:22:55
User closed query 'Per ETRTR: Symptoms prior to Illness Visit Day 1 that that were reported (which were the trigger for visit) are expected to be recorded. Please add data as applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 04:22:48
Query 'Per ETRTR: Symptoms prior to Illness Visit Day 1 that that were reported (which were the trigger for visit) are expected to be recorded. Please add data as applicable, thanks.' answered with 'Symptoms prior to Illness Visit Day 1 are recorded under "Day 1 - 14 Oct 2020." This is the date COVID symptoms were reported to the site.' (Site from CRA).	Ayssa Valente (b) (4)	05 Nov 2020 17:58:22
Query 'Per ETRTR: Upon onset of Symptoms that triggered Illness visit, please update AE CRF page "Start date" data point with the day when subject started COVID symptoms, thanks.' answered with 'AE has been updated to the start date of COVID symptoms' (Site from CRA).	Ayssa Valente (b) (4)	05 Nov 2020 17:49:59
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:36:38
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:16
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User opened query 'Per ETRTR: Upon onset of Symptoms that triggered Illness visit, please update AE CRF page "Start date" data point with the day when subject started COVID symptoms, thanks.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 21:07:15

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[Date](#)

Audit	User	Time (GMT)
User opened query 'Per ETRTR: Symptoms prior to Illness Visit Day 1 that that were reported (which were the trigger for visit) are expected to be recorded. Please add data as applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 21:05:37
User entered '15 Oct 2020'	Erin Harrelson (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '0'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '96'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
User entered '%'	System	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '101.1' F	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Moderate (Moderate)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Moderate (Moderate)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Moderate (Moderate)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Moderate (Moderate)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Moderate (Moderate)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Moderate (Moderate)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Moderate (Moderate)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Moderate (Moderate)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Moderate (Moderate)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Moderate (Moderate)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:59:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Moderate (Moderate)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:47:04

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	08 Jan 2021 12:59:13
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
User entered 'Day 2 (Day 2)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '16 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '0'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '99'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
User entered '%'	System	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '98.9' F	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Mild (Mild)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Mild (Mild)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Mild (Mild)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Mild (Mild)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Mild (Mild)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:59:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:37:29

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	08 Jan 2021 12:59:13
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
User entered 'Day 3 (Day 3)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '17 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '0'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '96'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
User entered '%'	System	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '98.4' F	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Mild (Mild)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Mild (Mild)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Mild (Mild)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Mild (Mild)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Mild (Mild)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:59:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:40:05

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	08 Jan 2021 12:59:13
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6) (b) (4)	09 Nov 2020 15:55:54
User entered 'Day 4 (Day 4)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '18 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '0'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '98'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
User entered '%'	System	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '99.6' F	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Mild (Mild)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User closed query 'Source note Mild Fatigue. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 14:14:12
Query 'Source note Mild Fatigue. Please reconcile.' answered with 'data has been corrected' (Site from CRA).	Erin Harrelson (b) (4) (b) (4)	26 Oct 2020 19:43:17
User entered 'Mild (Mild)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	26 Oct 2020 19:43:06
User opened query 'Source note Mild Fatigue. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 15:40:59
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 15:40:17
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Mild (Mild)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Mild (Mild)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Mild (Mild)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:59:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Oct 2020 17:41:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Ayssa Valente (b) (4)	08 Jan 2021 12:59:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
User entered 'Day 5 (Day 5)'	Erin Harrelson (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '19 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User closed query 'Per CDM: Please reconcile the Symptom Log for Day 7 by either deleting all instances of Not Done and keep Assessment Not Done box ticked. Otherwise verify if symptoms exist in source that were not captured in EDC and capture them accordingly.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 11:50:23
Query 'Per CDM: Please reconcile the Symptom Log for Day 7 by either deleting all instances of Not Done and keep Assessment Not Done box ticked. Otherwise verify if symptoms exist in source that were not captured in EDC and capture them accordingly.' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4)	19 Apr 2021 14:49:10
User opened query 'Per CDM: Please reconcile the Symptom Log for Day 7 by either deleting all instances of Not Done and keep Assessment Not Done box ticked. Otherwise verify if symptoms exist in source that were not captured in EDC and capture them accordingly.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 04:13:57
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '1'	Erin Harrelson (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered missing code ND - Not Done.	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User entered empty.	System	19 Apr 2021 14:48:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
User entered '%'	System	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered missing code ND - Not Done.	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Not Done (Not Done)'	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Not Done (Not Done)'	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Not Done (Not Done)'	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Not Done (Not Done)'	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Not Done (Not Done)'	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Not Done (Not Done)'	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Not Done (Not Done)'	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Not Done (Not Done)'	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Not Done (Not Done)'	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Not Done (Not Done)'	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Not Done (Not Done)'	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Not Done (Not Done)'	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Not Done (Not Done)'	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Not Done (Not Done)'	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Not Done (Not Done)'	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:59:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 14:48:25
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Not Done (Not Done)'	Erin Harrelson (b) (4) (b) (4)	20 Oct 2020 13:15:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	08 Jan 2021 12:59:13
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
User entered 'Day 6 (Day 6)'	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '20 Oct 2020'	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '0'	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '98'	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
User entered '%'	System	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered '98.6' F	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Mild (Mild)'	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Mild (Mild)'	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Morgan Mathis (b) (4)	21 Oct 2020 15:55:07
	(b) (4)	

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Mild (Mild)'	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'Mild (Mild)'	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:59:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:22:12
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:55:07

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Ayssa Valente (b) (4)	08 Jan 2021 12:59:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
User entered 'Day 7 (Day 7)'	Erin Harrelson (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered '21 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered '0'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered '98'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
User entered '%'	System	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered '98.4' F	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'Mild (Mild)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:59:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:19:12

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered 'Day 10 (Day 10)' reason for change:	(b) (4)	
Data Entry Error	Ayssa Valente (b) (4)	08 Jan 2021 12:59:13
DataPoint activated with code reason code Data	(b) (4)	
required.	(b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not	(b) (4), (b) (6)	09 Nov 2020 15:55:54
required.	(b) (4)	
User entered 'Day 8 (Day 8)'	Erin Harrelson (b) (4)	23 Oct 2020 12:20:42
	(b) (4)	

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User closed query 'Per CDM: Log must be completed for 14 days or until symptoms resolve whichever is later for participants that are confirmed SARs-CoV-2 positive based on the date of Illness Day 1. Please reconcile this symptom log. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 11:17:16
Query 'Per CDM: Log must be completed for 14 days or until symptoms resolve whichever is later for participants that are confirmed SARs-CoV-2 positive based on the date of Illness Day 1. Please reconcile this symptom log. ' answered with 'Despite multiple attempts, patient was not contacted for illness visits after 22Oct2020. Pt. was given schedule at next appt for future phone calls and advised to answer. Deviation was recorded and symptom log was updated to include the rest of illness visits as assessment not done. ' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:24:21
User opened query 'Per CDM: Log must be completed for 14 days or until symptoms resolve whichever is later for participants that are confirmed SARs-CoV-2 positive based on the date of Illness Day 1. Please reconcile this symptom log. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 04:16:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User closed query 'Please review and reconcile Illness days 9-14 as they aren't present in EDC. Daily calls are to be reported in EDC within 24 hrs of call completed. Daily calls are not to stop until symptoms stop or Illness Day 14 whichever is later per protocol.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 04:23:10

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

Date

Audit	User	Time (GMT)
Query 'Please review and reconcile Illness days 9-14 as they aren't present in EDC. Daily calls are to be reported in EDC within 24 hrs of call completed. Daily calls are not to stop until symptoms stop or Illness Day 14 whichever is later per protocol.' answered with 'Site inadvertently stopped contacting this subject on 22 Oct 2020 when their symptoms subsided.' (Site from CRA).	Ayssa Valente (b) (4)	05 Nov 2020 17:47:41
User opened query 'Please review and reconcile Illness days 9-14 as they aren't present in EDC. Daily calls are to be reported in EDC within 24 hrs of call completed. Daily calls are not to stop until symptoms stop or Illness Day 14 whichever is later per protocol.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 14:15:35
User entered '22 Oct 2020'	Erin Harrelson (b) (4)	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered '0'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered '98'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
User entered '%'	System	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered '98.3' F	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:59:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:57:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 15:55:54
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	23 Oct 2020 12:20:42

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User entered 'Day 2 (Day 2)' reason for change:	(b) (4)	
Data Entry Error	Ayssa Valente (b) (4)	16 Mar 2021 11:50:56
DataPoint activated with code reason code Data	(b) (4)	
required.	Ayssa Valente (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not	(b) (4)	
required.	Brandy Lowman (b) (4)	09 Nov 2020 15:13:14
User entered 'Day 1 (Day 1)'	(b) (4)	
	Ayssa Valente (b) (4)	05 Nov 2020 17:56:37
	(b) (4)	

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User closed query 'Per CDM: it appears there are two records for Day 1 with dates of 14OCT2020 and 15OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:51:50
Query 'Per CDM: it appears there are two records for Day 1 with dates of 14OCT2020 and 15OCT2020. Please reconcile or clarify.' answered with 'updated ' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	16 Mar 2021 11:51:43
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4) (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	Brandy Lowman (b) (4) (b) (4)	09 Nov 2020 15:13:14
User opened query 'Per CDM: it appears there are two records for Day 1 with dates of 14OCT2020 and 15OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 00:39:45
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered '14 Oct 2020'	Ayssa Valente (b) (4) (b) (4)	05 Nov 2020 17:56:37

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User closed query 'Per CDM: Assessment Not Done is checked however there is data present on this form. Assessment Not Done should only be selected if the entire assessment was not completed. Please reconcile the Symptom Log for Day 2 and update EDC accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 11:18:04
Query 'Per CDM: Assessment Not Done is checked however there is data present on this form. Assessment Not Done should only be selected if the entire assessment was not completed. Please reconcile the Symptom Log for Day 2 and update EDC accordingly.' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:19:45
User opened query 'Per CDM: Assessment Not Done is checked however there is data present on this form. Assessment Not Done should only be selected if the entire assessment was not completed. Please reconcile the Symptom Log for Day 2 and update EDC accordingly.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 04:10:32
User signature succeeded.	Barton Williams (b) (4) (b) (4)	16 Apr 2021 12:34:34
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 13:33:57
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	16 Mar 2021 11:50:56
User entered '1' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	16 Mar 2021 11:50:56
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4) (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	Brandy Lowman (b) (4) (b) (4)	09 Nov 2020 15:13:14
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered '0'	Ayssa Valente (b) (4) (b) (4)	05 Nov 2020 17:56:37

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint activated with code reason code Data required.	(b) (4) Ayssa Valente (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	Brandy Lowman (b) (4)	09 Nov 2020 15:13:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered missing code ND - Not Done.	Ayssa Valente (b) (4)	05 Nov 2020 17:56:37

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User entered empty.	System	19 Apr 2021 15:17:54
DataPoint activated with code reason code Data required.	Ayssa Valente (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Brandy Lowman (b) (4)	09 Nov 2020 15:13:14
	(b) (4)	
User entered '%'	System	05 Nov 2020 17:56:37

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint activated with code reason code Data required.	(b) (4) Ayssa Valente (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	Brandy Lowman (b) (4)	09 Nov 2020 15:13:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered missing code ND - Not Done.	Ayssa Valente (b) (4)	05 Nov 2020 17:56:37

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint activated with code reason code Data required.	(b) (4) Ayssa Valente (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	Brandy Lowman (b) (4)	09 Nov 2020 15:13:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'Moderate (Moderate)'	Ayssa Valente (b) (4)	05 Nov 2020 17:56:37

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint activated with code reason code Data required.	(b) (4) Ayssa Valente (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	Brandy Lowman (b) (4)	09 Nov 2020 15:13:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'Moderate (Moderate)'	Ayssa Valente (b) (4)	05 Nov 2020 17:56:37

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint activated with code reason code Data required.	(b) (4) Ayssa Valente (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	Brandy Lowman (b) (4)	09 Nov 2020 15:13:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'Moderate (Moderate)'	Ayssa Valente (b) (4)	05 Nov 2020 17:56:37

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint activated with code reason code Data required.	(b) (4) Ayssa Valente (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	Brandy Lowman (b) (4)	09 Nov 2020 15:13:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'Not Done (Not Done)'	(b) (4) Ayssa Valente (b) (4)	05 Nov 2020 17:56:37

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint activated with code reason code Data required.	(b) (4) Ayssa Valente (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	Brandy Lowman (b) (4)	09 Nov 2020 15:13:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'Not Done (Not Done)'	Ayssa Valente (b) (4)	05 Nov 2020 17:56:37
	(b) (4)	

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint activated with code reason code Data required.	(b) (4) Ayssa Valente (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	Brandy Lowman (b) (4)	09 Nov 2020 15:13:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'Not Done (Not Done)'	Ayssa Valente (b) (4)	05 Nov 2020 17:56:37

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint activated with code reason code Data required.	(b) (4) Ayssa Valente (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	Brandy Lowman (b) (4)	09 Nov 2020 15:13:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'Not Done (Not Done)'	Ayssa Valente (b) (4)	05 Nov 2020 17:56:37
	(b) (4)	

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint activated with code reason code Data required.	(b) (4) Ayssa Valente (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	Brandy Lowman (b) (4)	09 Nov 2020 15:13:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'Not Done (Not Done)'	Ayssa Valente (b) (4)	05 Nov 2020 17:56:37

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint activated with code reason code Data required.	(b) (4) Ayssa Valente (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	Brandy Lowman (b) (4)	09 Nov 2020 15:13:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'Not Done (Not Done)'	Ayssa Valente (b) (4)	05 Nov 2020 17:56:37
	(b) (4)	

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint activated with code reason code Data required.	(b) (4) Ayssa Valente (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	Brandy Lowman (b) (4)	09 Nov 2020 15:13:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'Not Done (Not Done)'	Ayssa Valente (b) (4)	05 Nov 2020 17:56:37

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint activated with code reason code Data required.	(b) (4) Ayssa Valente (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	Brandy Lowman (b) (4)	09 Nov 2020 15:13:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'Moderate (Moderate)'	Ayssa Valente (b) (4)	05 Nov 2020 17:56:37

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint activated with code reason code Data required.	(b) (4) Ayssa Valente (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	Brandy Lowman (b) (4)	09 Nov 2020 15:13:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'Not Done (Not Done)'	Ayssa Valente (b) (4)	05 Nov 2020 17:56:37

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint activated with code reason code Data required.	(b) (4) Ayssa Valente (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	Brandy Lowman (b) (4)	09 Nov 2020 15:13:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'Not Done (Not Done)'	Ayssa Valente (b) (4)	05 Nov 2020 17:56:37

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint activated with code reason code Data required.	(b) (4) Ayssa Valente (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	Brandy Lowman (b) (4)	09 Nov 2020 15:13:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'Not Done (Not Done)'	Ayssa Valente (b) (4)	05 Nov 2020 17:56:37

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint activated with code reason code Data required.	(b) (4) Ayssa Valente (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	Brandy Lowman (b) (4)	09 Nov 2020 15:13:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'Not Done (Not Done)'	(b) (4) Ayssa Valente (b) (4)	05 Nov 2020 17:56:37

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:59:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
DataPoint Un-verified.	Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
Signature has been broken.	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Apr 2021 15:17:54
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint activated with code reason code Data required.	(b) (4) Ayssa Valente (b) (4)	16 Mar 2021 11:50:38
DataPoint inactivated with code reason code Data not required.	Brandy Lowman (b) (4)	09 Nov 2020 15:13:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:12:34
User entered 'Not Done (Not Done)'	(b) (4) Ayssa Valente (b) (4)	05 Nov 2020 17:56:37

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:59:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User closed query 'Per CDM: Symptom Day 2 is missing. Please confirm whether Day 2 (14OCT2020) was not done or else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 17:51:56
Query 'Per CDM: Symptom Day 2 is missing. Please confirm whether Day 2 (14OCT2020) was not done or else clarify.' answered with 'Assessment for Day 2 added to eCRF.' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	16 Mar 2021 11:52:12
User opened query 'Per CDM: Symptom Day 2 is missing. Please confirm whether Day 2 (14OCT2020) was not done or else clarify.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 20:27:35
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:58:34
User entered 'Day 1 (Day 1)'	Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

**US3082247**

**Folder: Covid-19 Assessment 14 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:59:26**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:01:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered '13 Oct 2020'	(b) (4) Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:59:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:01:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered 'l'	(b) (4) Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

**US3082247**

**Folder: Covid-19 Assessment 14 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:59:26**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:01:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User entered empty.	System	08 Jan 2021 12:58:34

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:59:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:01:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:59:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:01:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

**US3082247**

**Folder: Covid-19 Assessment 14 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:59:26**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:01:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:59:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:01:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:59:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:01:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

**US3082247**

**Folder: Covid-19 Assessment 14 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:59:26**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:01:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

**US3082247**

**Folder: Covid-19 Assessment 14 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:59:26**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:01:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

**US3082247**

**Folder: Covid-19 Assessment 14 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:59:26**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:01:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

**US3082247**

**Folder: Covid-19 Assessment 14 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:59:26**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:01:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

**US3082247**

**Folder: Covid-19 Assessment 14 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:59:26**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:01:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

**US3082247**

**Folder: Covid-19 Assessment 14 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:59:26**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:01:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

**US3082247**

**Folder: Covid-19 Assessment 14 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:59:26**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:01:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:59:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:01:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

**US3082247**

**Folder: Covid-19 Assessment 14 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:59:26**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:01:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:59:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:01:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:59:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:01:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

**US3082247**

**Folder: Covid-19 Assessment 14 Oct 2020**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:59:26**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:01:41
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Ayssa Valente (b) (4) (b) (4)	08 Jan 2021 12:58:34

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
User entered 'Day 11 (Day 11)'	Erin Harrelson (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered '23 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered 'l'	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User entered empty.	System	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:59:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
User entered 'Day 12 (Day 12)'	Erin Harrelson (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered '24 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered 'I'	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User entered empty.	System	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:59:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:25:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
User entered 'Day 13 (Day 13)'	Erin Harrelson (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered '25 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered '1' reason for change: Data Entry Error	Erin Harrelson (b) (4)	19 Apr 2021 15:35:17
User entered '0'	(b) (4) Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User entered empty.	System	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:59:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:34:48

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
User entered 'Day 14 (Day 14)'	Erin Harrelson (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered '26 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered 'I'	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User entered empty.	System	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:59:26

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:25:49
User entered empty.	Erin Harrelson (b) (4) (b) (4)	19 Apr 2021 15:35:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:59:26

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:45:09
User entered '15 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:54:17

**US3082247**

**Folder: Covid-19 Assessment 14 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 21:59:26**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:45:09
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:54:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:59:26

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:45:09
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)	20 Oct 2020 09:41:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 09:08:01
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 'confirmed test result positive' (Site from System).	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:22:46
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	17 Oct 2020 21:22:13
User entered 'Yes (Y)' reason for change: New Information	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:22:13
Query 'Data is required. Please complete.' answered with 'Has not received results yet' (Site from System).	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 18:34:07
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 12:54:17
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:54:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:59:26

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:45:09
User entered '15 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:54:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:59:26

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:45:09
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:54:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:59:26

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:45:09
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:54:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:59:26

[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)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User closed query 'Please confirm response as a result is captured in the Preclarus portal and Viracor would be considered the central lab vendor of this test.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:08:37
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:51:47
Query 'Please confirm response as a result is captured in the Preclarus portal and Viracor would be considered the central lab vendor of this test.' answered with 'DIAGNOSTIC TEST WAS PERFORMED AT STUDY CENTRAL LAB' (Site from CRA).	Erin Harrelson (b) (4) (b) (4)	29 Oct 2020 11:56:51
DataPoint Un-verified.	Erin Harrelson (b) (4) (b) (4)	29 Oct 2020 11:56:31
User entered 'No (N)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	29 Oct 2020 11:56:31
User opened query 'Please confirm response as a result is captured in the Preclarus portal and Viracor would be considered the central lab vendor of this test.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 04:38:02
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:45:09
User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	19 Oct 2020 15:22:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandy Lowman (b) (4) (b) (4)	19 Oct 2020 15:22:25
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	17 Oct 2020 21:22:13
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Oct 2020 12:54:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:59:26

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:51:47
DataPoint Un-verified.	Erin Harrelson (b) (4)	29 Oct 2020 11:56:31
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	29 Oct 2020 11:56:31
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:45:09
User entered 'Vira-cor' reason for change: New Information	Flo Abbott (b) (4)	17 Oct 2020 21:22:13
User entered empty.	(b) (4) Erin Harrelson (b) (4)	16 Oct 2020 12:54:17
	(b) (4)	

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:59:26

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:51:47
DataPoint Un-verified.	Erin Harrelson (b) (4)	29 Oct 2020 11:56:31
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	29 Oct 2020 11:56:31
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:45:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Flo Abbott (b) (4)	17 Oct 2020 21:22:13
User entered empty.	(b) (4) Erin Harrelson (b) (4)	16 Oct 2020 12:54:17

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:59:26

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User entered 'I'	System	17 Oct 2020 21:22:13

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	06 Nov 2020 10:49:06
Query 'Data is required. Please complete.' answered with 'Data was not collected' (Site from System).	Alice Cipollini (b) (4) (b) (4)	05 Nov 2020 17:40:33
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 15:58:31
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 17:41:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 17:41:21
User entered 'No (N)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	05 Nov 2020 17:41:21
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 15:58:31
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 17:41:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 17:41:21
User entered 'No (N)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	05 Nov 2020 17:41:21
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 15:58:31
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	06 Nov 2020 10:49:15
Query 'Data is required. Please complete.' answered with 'Data not collected ' (Site from System).	Alice Cipollini (b) (4) (b) (4)	05 Nov 2020 17:40:57
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 15:58:31
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 17:41:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 17:41:21
User entered 'No (N)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	05 Nov 2020 17:41:21
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 15:58:31
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 17:41:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 17:41:21
User entered 'No (N)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	05 Nov 2020 17:41:21
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 15:58:31
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:02:38
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User closed query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:54:00
Query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia and update accordingly.' answered with 'Evidence of shock and pneumonia updated accordingly.' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	05 Jan 2021 12:57:02
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	05 Jan 2021 12:56:32
User entered 'No (N)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	05 Jan 2021 12:56:32
User opened query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia and update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 06:17:33
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

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Generated On: 11 Aug 2021 21:59:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:02:43
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Un-verified.	(b) (4) Ayssa Valente (b) (4)	05 Jan 2021 12:56:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	05 Jan 2021 12:56:32
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 17:41:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 17:41:21
User entered 'No (N)' reason for change: Data Entry Error	Alice Cipollini (b) (4) (b) (4)	05 Nov 2020 17:41:21
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 15:58:31
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:59:26

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 17:13:06
User entered empty.	Morgan Mathis (b) (4) (b) (4)	21 Oct 2020 15:58:31

US3082247

Folder: Covid-19 Assessment 14 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 21:59:26

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:44:23
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:03:02
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered 'No (N)'	(b) (4) Erin Harrelson (b) (4) (b) (4)	10 Dec 2020 20:42:08

**US3082247**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User accepted default value 'Day 3 (Day 3)'	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

**US3082247**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:58:59
User entered 'No (N)'	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

**US3082247**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:58:59
User entered empty.	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

**US3082247**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 21:59:26**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User accepted default value 'Day 5 (Day 5)'	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

**US3082247**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 21:59:26**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:58:59
User entered 'No (N)'	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

**US3082247**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 21:59:26**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:58:59
User entered empty.	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

**US3082247**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 21:59:26**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User accepted default value 'Day 7 (Day 7)'	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

**US3082247**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 21:59:26**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:58:59
User entered 'No (N)'	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

**US3082247**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 21:59:26**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:58:59
User entered empty.	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

**US3082247**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 21:59:26**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User accepted default value 'Day 9 (Day 9)'	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

**US3082247**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 21:59:26**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:58:59
User entered 'No (N)'	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

**US3082247**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 21:59:26**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:58:59
User entered empty.	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

**US3082247**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 21:59:26**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User accepted default value 'Day 14 (Day 14)'	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

**US3082247**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 21:59:26**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:58:59
User entered 'No (N)'	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

**US3082247**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 21:59:26**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:58:59
User entered empty.	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

**US3082247**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 21:59:26**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User accepted default value 'Day 21 (Day 21)'	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

**US3082247**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 21:59:26**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:58:59
User entered 'No (N)'	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

**US3082247**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 21:59:26**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:58:59
User entered empty.	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

**US3082247**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 21:59:26**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User accepted default value 'Day 28 (Day 28)'	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

US3082247

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:59:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:04:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Un-verified.	(b) (4) Ayssa Valente (b) (4)	18 Nov 2020 20:41:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	18 Nov 2020 20:41:13
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:58:59
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 15:05:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 15:05:30
User entered 'No (N)' reason for change: Data Entry Error	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:30
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 15:05:21
User entered empty; reason for change Data Entry Error	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:21
User entered 'No (N)'	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

**US3082247**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 21:59:26**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:04:58
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Un-verified.	(b) (4) Ayssa Valente (b) (4)	20 Nov 2020 13:24:11
User entered '11 Nov 2020' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	20 Nov 2020 13:24:11
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:58:59
User entered empty.	Megan Marles (b) (4) (b) (4)	09 Nov 2020 15:05:11

US3082247

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:59:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thank you for the update, however date of collection is missing for Day 28 in saliva log. Please update date of collection as 11Nov2020 as its reported in PPD central lab.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 07:57:00
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thank you for the update, however date of collection is missing for Day 28 in saliva log. Please update date of collection as 11Nov2020 as its reported in PPD central lab.' answered with 'date of collection added' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	20 Nov 2020 13:24:42
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thank you for the update, however date of collection is missing for Day 28 in saliva log. Please update date of collection as 11Nov2020 as its reported in PPD central lab.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 04:12:55
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11NOV2020 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)	20 Nov 2020 04:12:55
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11NOV2020 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 'Saliva collection log has been updated for Day 28.' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	18 Nov 2020 20:42:10
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11NOV2020 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)	18 Nov 2020 12:21:59

**US3082247**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:52:28
User entered 'Yes (Y)'	Flo Abbott (b) (4)	19 Oct 2020 17:32:31
	(b) (4)	

US3082247

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:59:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User closed query 'Re-Query: Data isn't entered as saliva log is completely blank. Please reconcile and enter page as multiple samples should have been collected to date.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 02:04:52
Query 'Re-Query: Data isn't entered as saliva log is completely blank. Please reconcile and enter page as multiple samples should have been collected to date.' answered with 'Saliva samples not collected, NP swab was performed and patient was positive. Saliva Collection data is correct.' (Site from CRA).	Brandy Lowman (b) (4) (b) (4)	09 Nov 2020 15:16:25
User opened query 'Re-Query: Data isn't entered as saliva log is completely blank. Please reconcile and enter page as multiple samples should have been collected to date.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 01:36:36
User closed query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 01:36:36
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:52:28
Query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' answered with 'DATE ENTERED' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:38:55
User opened query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 21:03:12
User entered '15 Oct 2020'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:32:31

**US3082247**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

[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 16:08:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:52:28
User entered 'Home (Home)'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:32:31

**US3082247**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User entered 'SICKD1'	System	19 Oct 2020 17:32:31

**US3082247**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:40:20
User entered 'Yes (Y)'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:29:20

**US3082247**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:40:20
User entered '15 Oct 2020'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:29:20

**US3082247**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:40:20
User entered '17:04'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:29:20

US3082247

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User entered '15 Oct 2020 17:04'	System	19 Oct 2020 17:29:20

US3082247

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:40:20
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Oct 2020 18:02:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Angie Northcott (b) (4) (b) (4)	19 Oct 2020 18:02:26
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Oct 2020 17:33:23
User entered 'Not done' (non-conformant).	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:33:23
DataPoint set to visible.	System	19 Oct 2020 17:32:31

US3082247

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:40:20
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Oct 2020 18:02:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Angie Northcott (b) (4) (b) (4)	19 Oct 2020 18:02:26
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Oct 2020 17:33:23
User entered 'Not done' (non-conformant).	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:33:23
DataPoint set to visible.	System	19 Oct 2020 17:32:31

US3082247

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:40:20
User entered '98.9' F	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:29:20

US3082247

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:40:20
User closed query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	System	19 Oct 2020 17:30:33
User opened query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	System	19 Oct 2020 17:29:20
User entered 'Oral (Oral)'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:29:20

**US3082247**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:40:20
User entered empty; reason for change Data Entry Error	Flo Abbott (b) (4)	19 Oct 2020 17:30:33
User entered 'This was done as a phone call'	(b) (4)	
	Flo Abbott (b) (4)	19 Oct 2020 17:29:20
	(b) (4)	

US3082247

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:40:20
User closed query 'Per ETRTR: Please confirm rationale for not performing Vitals collection for Pulse, Resp. Rate and Blood Pressure, thanks.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 13:50:25
Query 'Per ETRTR: Please confirm rationale for not performing Vitals collection for Pulse, Resp. Rate and Blood Pressure, thanks.' answered with 'It was not done in error.' (Site from CRA).	Alice Cipollini (b) (4) (b) (4)	22 Oct 2020 15:10:56
User opened query 'Per ETRTR: Please confirm rationale for not performing Vitals collection for Pulse, Resp. Rate and Blood Pressure, thanks.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 21:02:35
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 18:35:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Oct 2020 18:35:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	19 Oct 2020 18:35:02
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 17:29:20
User entered empty.	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:29:20

**US3082247**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User entered 'bpm'	System	19 Oct 2020 18:35:02
User entered empty.	System	19 Oct 2020 17:29:20

US3082247

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:40:20
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 18:35:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Oct 2020 18:35:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	19 Oct 2020 18:35:02
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 17:29:20
User entered empty.	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:29:20

**US3082247**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User entered 'breaths/min'	System	19 Oct 2020 18:35:02
User entered empty.	System	19 Oct 2020 17:29:20

US3082247

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:40:20
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 18:35:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Oct 2020 18:35:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	19 Oct 2020 18:35:02
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 17:29:20
User entered empty.	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:29:20

US3082247

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User entered 'mmHg'	System	19 Oct 2020 18:35:02
User entered empty.	System	19 Oct 2020 17:29:20

US3082247

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:40:20
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 18:35:02
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	19 Oct 2020 18:35:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	19 Oct 2020 18:35:02
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 17:29:20
User entered empty.	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:29:20

**US3082247**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User entered 'mmHg'	System	19 Oct 2020 18:35:02
User entered empty.	System	19 Oct 2020 17:29:20

**US3082247**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54

**US3082247**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54

US3082247

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:59:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:40:32
User entered 'No (N)'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:31:29

**US3082247**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:59:26**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:40:32
User entered empty.	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:31:29

US3082247

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:59:26

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:40:41
User entered 'Yes (Y)'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:31:54

**US3082247**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 21:59:26**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:54
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:40:41
User entered '15 Oct 2020'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:31:54

**US3082247**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:58:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:47:50

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:59:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	(b) (4)	
	System	14 Dec 2020 20:14:17
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	14 Dec 2020 19:50:20
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:58:40
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 16:47:50

**US3082247**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

[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 16:17:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:58:40
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Nov 2020 16:47:50

**US3082247**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User entered 'SICKD28'	System	11 Nov 2020 16:47:50

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:50:17

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	14 Dec 2020 20:14:17
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 19:50:20
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:59:02
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 16:50:17

**US3082247**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:02
User entered '09:45'	(b) (4), (b) (6)	11 Nov 2020 16:50:17

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User entered '11 Nov 2020 09:45'	System	11 Nov 2020 16:50:17

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:02
User entered '66.5' in	(b) (4), (b) (6)	11 Nov 2020 16:50:17
DataPoint set to visible.	System	11 Nov 2020 16:47:50

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:02
User entered '171' lb	(b) (4), (b) (6)	11 Nov 2020 16:50:17
DataPoint set to visible.	System	11 Nov 2020 16:47:50

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:02
User entered '98.2' F	(b) (4), (b) (6)	11 Nov 2020 16:50:17

**US3082247**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:59:26**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:02
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Nov 2020 16:50:17

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:02
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:50:17

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:02
User entered '68'	(b) (4), (b) (6)	11 Nov 2020 16:50:17

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User entered 'bpm'	System	11 Nov 2020 16:50:17

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:02
User entered '18'	(b) (4), (b) (6)	11 Nov 2020 16:50:17

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User entered 'breaths/min'	System	11 Nov 2020 16:50:17

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:02
User entered '120'	(b) (4), (b) (6)	11 Nov 2020 16:50:17

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User entered 'mmHg'	System	11 Nov 2020 16:50:17

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:02
User entered '62'	(b) (4), (b) (6)	11 Nov 2020 16:50:17

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User entered 'mmHg'	System	11 Nov 2020 16:50:17

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:59:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:59:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:05:34
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:50:32

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:59:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:05:34
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4)	14 Dec 2020 20:14:17
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	14 Dec 2020 19:50:20
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 16:50:32

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:59:26

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:50:47

US3082247

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:59:26

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:28
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:20
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 16:50:47

US3082247

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

Form: Visit Date

Generated On: 11 Aug 2021 21:59:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:45:11
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User closed query 'Per CDM : Was this visit performed Yes/ No should be provided. thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 07:08:39
Query 'Per CDM : Was this visit performed Yes/ No should be provided. thanks ' answered with 'No, participant never responded after multiple attempts' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 17:23:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 17:23:24
User opened query 'Per CDM : Was this visit performed Yes/ No should be provided. thanks ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 08:58:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Apr 2021 08:56:22
Query 'Data is required. Please complete.' answered with 'to remove visit from file, nothing is checked for this visit ' (Site from System).	Angie Northcott (b) (4) (b) (4)	09 Apr 2021 13:08:34
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 13:08:07
User entered empty; reason for change Data Entry Error	Angie Northcott (b) (4) (b) (4)	09 Apr 2021 13:08:07
Comment added 'Participant terminated due to loss to follow up'.	(b) (4), (b) (6)	30 Mar 2021 19:14:39
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 19:13:43

**US3082247**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:45:11
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:13:43

**US3082247**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:45:11
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:13:43

**US3082247**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:59:26**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User entered 'UNBLND_DECIDE'	System	12 Apr 2021 17:23:24
User entered empty.	System	09 Apr 2021 13:08:07
User entered 'UNBLND_DECIDE'	System	30 Mar 2021 19:13:43

**US3082247**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:59:26**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:28:05
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:15:16

US3082247

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

Form: Unblinding

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:28:05
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User closed query 'Per CDM: 'NA unblinded under A5 and study discontinued' is not ticked and consent date is blank. Please review as one of these fields should be completed. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 07:10:06
Query 'Per CDM: 'NA unblinded under A5 and study discontinued' is not ticked and consent date is blank. Please review as one of these fields should be completed. ' answered with 'Updated. ' (Site from DM).	Megan Marles (b) (4) (b) (4)	13 Apr 2021 18:09:35
User entered '1' reason for change: Data Entry Error	Megan Marles (b) (4) (b) (4)	13 Apr 2021 18:08:55
User opened query 'Per CDM: 'NA unblinded under A5 and study discontinued' is not ticked and consent date is blank. Please review as one of these fields should be completed. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 07:35:38
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 19:15:16

US3082247

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

Form: Unblinding

Generated On: 11 Aug 2021 21:59:26

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:28:05
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 20:44:36
User closed query 'Per CDM, per sponsor review: Subject was study discontinued prior to any possible unblinding, please agree to remove all data from all forms in this visit.'	(b) (4), (b) (6)	09 Apr 2021 20:44:32
(Site from DM).		
Query 'Data is required. Please complete.' answered with 'participant never completed OL day 1 visit' (Site from System).	Angie Northcott (b) (4)	09 Apr 2021 13:04:53
	(b) (4)	
Query 'Per CDM, per sponsor review: Subject was study discontinued prior to any possible unblinding, please agree to remove all data from all forms in this visit.'	Angie Northcott (b) (4)	09 Apr 2021 13:03:43
	(b) (4)	
' answered with 'updated' (Site from DM).		
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 13:03:21
User entered empty; reason for change Data Entry Error	Angie Northcott (b) (4)	09 Apr 2021 13:03:21
	(b) (4)	
User opened query 'Per CDM, per sponsor review: Subject was study discontinued prior to any possible unblinding, please agree to remove all data from all forms in this visit.'	(b) (4), (b) (6)	09 Apr 2021 06:21:48
(Site from DM).		
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 19:15:16

**US3082247**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:59:26**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:28:05
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:15:16

**US3082247**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:59:26**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:28:05
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:15:16

US3082247

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

Form: Unblinding

Generated On: 11 Aug 2021 21:59:26

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:28:05
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:15:16

**US3082247**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:59:26**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:28:05
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:15:16

**US3082247**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:59:26**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:28:05
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:15:16

**US3082247**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:59:26**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:28:05
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:15:16

**US3082247**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:59:26**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User entered empty.	System	30 Mar 2021 19:15:16

**US3082247**

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

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:59:26**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User entered empty.	System	30 Mar 2021 19:15:16

US3082247

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:59:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:45:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 08:52:09
Query 'Data is required. Please complete.' answered with 'visit not performed' (Site from System).	Angie Northcott (b) (4)	09 Apr 2021 13:07:16
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	09 Apr 2021 13:06:51
	Angie Northcott (b) (4)	09 Apr 2021 13:06:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:15:22

US3082247

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:59:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:45:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:15:22

**US3082247**

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

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:59:26**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:45:28
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:15:22

**US3082247**

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

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User entered empty.	System	30 Mar 2021 19:15:22

US3082247

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:59:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:45:35
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 08:59:05
Query 'Data is required. Please complete.' answered with 'visit not completed ' (Site from System).	Angie Northcott (b) (4)	09 Apr 2021 13:07:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	09 Apr 2021 13:07:23
User entered empty; reason for change Data Entry Error	Angie Northcott (b) (4)	09 Apr 2021 13:07:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:15:27

**US3082247**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:45:35
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:15:27

**US3082247**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:59:26**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:45:35
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:15:27

**US3082247**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User entered empty.	System	30 Mar 2021 19:15:27

**US3082247**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 21:59:26**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:17
User entered 'Yes (Y)'	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:23:36

**US3082247**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:35:08
User entered 'USA-US114-2020-mRNA-1273-P301000005'	System	19 Oct 2020 12:21:30
User entered 'New'	(b) (4), (b) (6)	19 Oct 2020 12:21:30

US3082247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:59:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
User closed query 'Per MM, please confirm this event is not a medically attended adverse event' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 11:38:28
Query 'Per MM, please confirm this event is not a medically attended adverse event' answered with 'Confirmed this was not medically attended' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	18 Nov 2020 20:50:12
User opened query 'Per MM, please confirm this event is not a medically attended adverse event' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 13:26:30
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:49:37
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) (b) (4)	17 Oct 2020 21:26:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 21:26:34
Data point term sent to Coder	System	17 Oct 2020 21:25:17
User entered 'Covid 19'	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

US3082247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:59:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 17:09:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 17:09:02
User entered 'No (N)' reason for change: Data Entry Error	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:09:02
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Oct 2020 21:25:03
User entered empty.	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

US3082247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:59:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 17:09:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 17:09:26
User entered 'No (N)' reason for change: Data Entry Error	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:09:26
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Oct 2020 21:25:03
User entered empty.	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

US3082247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:59:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered 'Yes (Y)'	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

US3082247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:59:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 12:34:51
User closed query 'PV Query: Please clarify onset date of the event. Onset date is provided as 15 Oct 2020 but the subject received Tylenol and ibuprofen for COVID-19 on 14 Oct 2020. Did the subject experience any COVID-19 symptoms prior to 15 Oct 2020? If yes, please consider updating the event onset date to onset date of the symptoms.' (Site from Safety).	(b) (4), (b) (6)	07 Nov 2020 01:55:19
Query 'PV Query: Please clarify onset date of the event. Onset date is provided as 15 Oct 2020 but the subject received Tylenol and ibuprofen for COVID-19 on 14 Oct 2020. Did the subject experience any COVID-19 symptoms prior to 15 Oct 2020? If yes, please consider updating the event onset date to onset date of the symptoms.' answered with 'UPDATED' (Site from Safety).	Morgan Mathis (b) (4) (b) (4)	05 Nov 2020 13:27:25
DataPoint Un-verified.	Morgan Mathis (b) (4) (b) (4)	05 Nov 2020 13:27:18
User entered '13 Oct 2020' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	05 Nov 2020 13:27:18
User opened query 'PV Query: Please clarify onset date of the event. Onset date is provided as 15 Oct 2020 but the subject received Tylenol and ibuprofen for COVID-19 on 14 Oct 2020. Did the subject experience any COVID-19 symptoms prior to 15 Oct 2020? If yes, please consider updating the event onset date to onset date of the symptoms.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 13:40:00
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered '15 Oct 2020'	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

**US3082247**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered empty.	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

**US3082247**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User entered empty.	System	17 Oct 2020 21:25:03

US3082247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:59:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 12:34:53
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	05 Nov 2020 13:27:33
DataPoint Un-verified.	Morgan Mathis (b) (4)	05 Nov 2020 13:27:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Morgan Mathis (b) (4)	05 Nov 2020 13:27:33
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	05 Nov 2020 13:27:18
DataPoint Verified.	System	05 Nov 2020 13:27:18
	(b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered 'Yes (Y)'	Flo Abbott (b) (4)	17 Oct 2020 21:25:03
	(b) (4)	

US3082247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:59:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 12:34:56
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)	07 Nov 2020 01:55:34
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'UPDATED.' (Site from Safety).	Morgan Mathis (b) (4) (b) (4)	05 Nov 2020 13:27:41
DataPoint Un-verified.	Morgan Mathis (b) (4) (b) (4)	05 Nov 2020 13:27:18
User entered '22 Oct 2020' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	05 Nov 2020 13:27:18
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)	23 Oct 2020 13:39:09
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered empty.	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

US3082247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:59:26

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 12:35:21
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	05 Nov 2020 13:27:53
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Nov 2020 13:27:53
User entered empty; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	05 Nov 2020 13:27:53
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	05 Nov 2020 13:27:33
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Nov 2020 13:27:18
DataPoint Un-verified.	Morgan Mathis (b) (4) (b) (4)	05 Nov 2020 13:27:18
User entered '17:' (non-conformant).	Morgan Mathis (b) (4)	05 Nov 2020 13:27:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered empty.	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

**US3082247**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User entered empty.	System	05 Nov 2020 13:27:53
User entered '22 Oct 2020 17:' (non-conformant).	System	05 Nov 2020 13:27:18
User entered empty.	System	17 Oct 2020 21:25:03

US3082247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:59:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 17:09:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 17:09:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:09:49
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Oct 2020 21:25:03
User entered empty.	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

US3082247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:59:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:44:36
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	14 Dec 2020 20:22:47
User entered 'No (N)' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	14 Dec 2020 20:22:47
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	14 Dec 2020 20:22:08
DataPoint Un-verified.	Morgan Mathis (b) (4) (b) (4)	14 Dec 2020 20:22:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	14 Dec 2020 20:22:08
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered 'No (N)'	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

**US3082247**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered '0'	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

**US3082247**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered '0'	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

**US3082247**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered '0'	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

**US3082247**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered empty.	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

**US3082247**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered empty.	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

**US3082247**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered empty.	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

**US3082247**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered empty.	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

**US3082247**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered '0'	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

**US3082247**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered '0'	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

**US3082247**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered '0'	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

US3082247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:59:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 17:10:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 17:10:15
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:10:15
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Oct 2020 21:25:03
User entered empty.	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

US3082247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:59:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 17:10:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 17:10:30
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:10:30
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Oct 2020 21:25:03
User entered empty.	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

US3082247

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 11:18:47
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'AE is COVID-19' (Site from System).	Ayssa Valente (b) (4) (b) (4)	12 Nov 2020 12:52:29
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	12 Nov 2020 12:50:01
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 12:35:30
User closed query 'Per CDM: If the patient will not receive further IP doses, then please complete the Dosing Discontinuation form. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 20:33:35
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	07 Nov 2020 01:56:01
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		06 Nov 2020 17:59:53
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	06 Nov 2020 17:59:53

US3082247

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per CDM: If the patient will not receive further IP doses, then please complete the Dosing Discontinuation form. Thank you.' answered with 'COMPLETED. ' (Site from DM).	Morgan Mathis (b) (4)	06 Nov 2020 17:57:01
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	06 Nov 2020 17:56:17
User opened query 'Per CDM: If the patient will not receive further IP doses, then please complete the Dosing Discontinuation form. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 16:48:50
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'UPDATED. ' (Site from Safety).	Morgan Mathis (b) (4)	05 Nov 2020 13:28:00
DataPoint Un-verified.	Morgan Mathis (b) (4)	05 Nov 2020 13:27:18
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Morgan Mathis (b) (4)	05 Nov 2020 13:27:18
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 13:39:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:49:37
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 17:11:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 17:11:25
User entered 'None (NONE)' reason for change: Data Entry Error	Flo Abbott (b) (4)	19 Oct 2020 17:11:25
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Oct 2020 21:25:03
User entered empty.	Flo Abbott (b) (4)	17 Oct 2020 21:25:03

US3082247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:59:26

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Oct 2020 17:11:25
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	17 Oct 2020 21:25:03
User entered '0'	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

US3082247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:59:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered '1' reason for change: Data Entry Error	Flo Abbott (b) (4)	19 Oct 2020 17:11:25
User entered '0'	(b) (4) Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

**US3082247**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered '0'	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

US3082247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:59:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 12:35:30
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)	07 Nov 2020 01:56:10
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).	Morgan Mathis (b) (4) (b) (4)	05 Nov 2020 13:28:10
DataPoint Un-verified.	Morgan Mathis (b) (4) (b) (4)	05 Nov 2020 13:27:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	05 Nov 2020 13:27:18
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)	23 Oct 2020 13:39:20
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:49:37
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 17:11:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 17:11:25
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:11:25
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Oct 2020 21:25:03
User entered empty.	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

**US3082247**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered empty.	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

US3082247

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:59:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4) System	14 Dec 2020 20:22:47
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	14 Dec 2020 20:22:47
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Dec 2020 20:22:08
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)	07 Nov 2020 01:56:14
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 HISTORY. ' (Site from Safety).	Morgan Mathis (b) (4) (b) (4)	05 Nov 2020 13:28:32
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)	23 Oct 2020 13:39:31
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:49:37
User entered empty.	Flo Abbott (b) (4) (b) (4)	17 Oct 2020 21:25:03

**US3082247**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User entered '0'	System	14 Dec 2020 20:22:47
User entered '1'	System	14 Dec 2020 20:22:08
User entered '0'	System	17 Oct 2020 21:25:03

**US3082247**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User entered '0'	System	19 Oct 2020 17:09:02

**US3082247**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:59:26

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:50:05
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:22:56

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:59:26

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
User closed query 'Source notes Vit C and Xicam. Please confirm if these should be added to the CM log.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:30:51
Query 'Source notes Vit C and Xicam. Please confirm if these should be added to the CM log.' answered with 'CM log has been updated. ' (Site from CRA).	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:19:12
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:52:38
User opened query 'Source notes Vit C and Xicam. Please confirm if these should be added to the CM log.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 15:51:37
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAVAGINAL CONTRACEPTIVES, PRODUCT: ETHINYLESTRADIOL;ETONOGESTREL, PRODUCTSYNONYM: NUVARING - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 06:47:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 06:47:58
Data point term sent to Coder	System	16 Sep 2020 13:44:09
Coding entries removed.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:44:08
User entered 'NUVARING [ETONOGESTREL/ETHINYL ESTRADIOL]' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:44:08
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAVAGINAL CONTRACEPTIVES, PRODUCT: ETHINYLESTRADIOL;ETONOGESTREL, PRODUCTSYNONYM: NUVARING - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 13:42:43

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:59:26

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	16 Sep 2020 13:42:43
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	16 Sep 2020 13:42:06
User entered 'Nuvaring'	Erin Harrelson (b) (4)	16 Sep 2020 13:41:51
	(b) (4)	

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:59:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
User closed query 'Per DM CLR: Indication = BIRTH CONTROL. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.	(b) (4) (b) (4), (b) (6)	08 Nov 2020 20:50:45
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:29:01
Query 'Per DM CLR: Indication = BIRTH CONTROL. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.	Erin Harrelson (b) (4)	06 Nov 2020 12:46:21
' answered with 'updated' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Erin Harrelson (b) (4)	06 Nov 2020 12:46:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Erin Harrelson (b) (4)	06 Nov 2020 12:46:09
User opened query 'Per DM CLR: Indication = BIRTH CONTROL. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.	(b) (4), (b) (6)	06 Nov 2020 10:42:57
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'No (N)'	Erin Harrelson (b) (4)	16 Sep 2020 13:41:51
	(b) (4)	

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'Birth Control'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:41:51

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered '0.12/0.015'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:41:51

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:59:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'mg (mg)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:41:51

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:59:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:41:51

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:59:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'other (OTHER)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:41:51

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:59:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'every 3 weeks'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:41:51

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:59:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'Vaginal (VAGINAL)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:41:51

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:59:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:41:51

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:59:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'UN UNK 2019'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:41:51

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered '0'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:41:51

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:59:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:41:51

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:41:51

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:59:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:41:51

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User entered empty.	System	16 Sep 2020 13:41:51

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User entered empty.	System	16 Sep 2020 13:41:51

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User entered empty.	System	16 Sep 2020 13:41:51

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:59:26

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 13:15:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 13:15:43
Data point term sent to Coder	System	16 Sep 2020 13:43:06
User entered 'Multivitamin'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:42:50

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:59:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:42:50

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:59:26**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'Nutritional Supplement'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:42:50

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:59:26**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'l'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:42:50

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:59:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'tablet (TABLET)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:42:50

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:59:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:42:50

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:59:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'once daily (QD)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:42:50

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:59:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:42:50

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:59:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'Oral (ORAL)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:42:50

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:59:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:42:50

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'UN UNK 2016'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:42:50

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:59:26**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered '0'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:42:50

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:59:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:42:50

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered empty.	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:42:50

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:59:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	16 Sep 2020 13:42:50

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:59:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User entered '1'	System	16 Sep 2020 13:42:50

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:59:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User entered '1'	System	16 Sep 2020 13:42:50

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:59:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User entered '804 (804)'	System	16 Sep 2020 13:42:50

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:59:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
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) (b) (4)	19 Oct 2020 17:19:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 17:19:23
Data point term sent to Coder	System	19 Oct 2020 17:14:48
User entered 'Tylenol'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:14:23

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:59:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'No (N)'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:14:23

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:59:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'Covid 19'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:14:23

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:59:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered '500'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:14:23

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:59:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'mg (mg)'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:14:23

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:59:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered empty.	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:14:23

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:59:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'other (OTHER)'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:14:23

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:59:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'Q4hr alternating with Ibuprofen'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:14:23

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:59:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'Oral (ORAL)'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:14:23

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:59:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered empty.	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:14:23

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:59:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
User closed query 'Per CDM CLR Re query: response noted, please clarify why the medication was taken before the AE. kindly confirm and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 20:48:53
Query 'Per CDM CLR Re query: response noted, please clarify why the medication was taken before the AE. kindly confirm and update accordingly.' answered with 'The start date of corresponding AE is 13 Oct 2020.' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	06 Nov 2020 13:18:15
User opened query 'Per CDM CLR Re query: response noted, please clarify why the medication was taken before the AE. kindly confirm and update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 12:25:02
User closed query 'Per DM CLR: The Con Med start date is prior to the start date of the AE. Please review and reconcile the Con Med and AE start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 12:24:56
Query 'Per DM CLR: The Con Med start date is prior to the start date of the AE. Please review and reconcile the Con Med and AE start dates as appropriate.' answered with 'Per pt report med was taken before dx of AE. Data is correct.' (Site from DM).	Brandy Lowman (b) (4) (b) (4)	02 Nov 2020 19:47:15
User opened query 'Per DM CLR: The Con Med start date is prior to the start date of the AE. Please review and reconcile the Con Med and AE start dates as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 15:43:00
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered '14 Oct 2020'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:14:23

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:59:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered '0'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:14:23

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:59:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:02
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:55:56
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated to add end date' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	16 Nov 2020 12:52:58
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	16 Nov 2020 12:52:41
User entered 'No (N)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	16 Nov 2020 12:52:41
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 10:05:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'Yes (Y)'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:14:23

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:02
DataPoint Un-verified.	Ayssa Valente (b) (4)	16 Nov 2020 12:52:41
User entered '22 Oct 2020' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	16 Nov 2020 12:52:41
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered empty.	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:14:23

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:59:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:07
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 17:14:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 17:14:31
User entered 'No (N)' reason for change: Data Entry Error	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:14:31
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 17:14:23
User entered empty.	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:14:23

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:59:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:07
User entered empty.	System	19 Oct 2020 17:14:23

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:59:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:07
User entered empty.	System	19 Oct 2020 17:14:23

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:59:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:07
User entered empty.	System	19 Oct 2020 17:14:23

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:59:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 17:19:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 17:19:25
Data point term sent to Coder	System	19 Oct 2020 17:16:54
User entered 'Ibuprofen'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:16:19

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:59:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'No (N)'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:16:19

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:59:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'Covid 19'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:16:19

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:59:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered '400'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:16:19

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:59:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'mg (mg)'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:16:19

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:59:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered empty.	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:16:19

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:59:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'other (OTHER)'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:16:19

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:59:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'Q4hr alternating with tyelnol'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:16:19

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:59:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'Oral (ORAL)'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:16:19

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:59:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered empty.	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:16:19

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:59:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
User closed query 'Per CDM CLR Re query: response noted, please clarify why the medication was taken before the AE. kindly confirm and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 20:53:09
Query 'Per CDM CLR Re query: response noted, please clarify why the medication was taken before the AE. kindly confirm and update accordingly.' answered with 'This is after the start date of AE. AE start date 13 Oct 2020.' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	06 Nov 2020 13:17:50
User opened query 'Per CDM CLR Re query: response noted, please clarify why the medication was taken before the AE. kindly confirm and update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 12:24:37
User closed query 'Per DM CLR: The Con Med start date is prior to the start date of the AE. Please review and reconcile the Con Med and AE start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 12:24:30
Query 'Per DM CLR: The Con Med start date is prior to the start date of the AE. Please review and reconcile the Con Med and AE start dates as appropriate.' answered with 'Per pt report con med was taken before beginning of AE. Data is correct.' (Site from DM).	Brandy Lowman (b) (4) (b) (4)	02 Nov 2020 19:47:41
User opened query 'Per DM CLR: The Con Med start date is prior to the start date of the AE. Please review and reconcile the Con Med and AE start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:45:57
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered '14 Oct 2020'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:16:19

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:59:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered '0'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:16:19

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:59:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:02
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:56:07
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated to add end date' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	16 Nov 2020 12:53:29
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	16 Nov 2020 12:53:21
User entered 'No (N)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	16 Nov 2020 12:53:21
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 10:05:51
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'Yes (Y)'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:16:19

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:02
DataPoint Un-verified.	Ayssa Valente (b) (4)	16 Nov 2020 12:53:21
User entered '22 Oct 2020' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	16 Nov 2020 12:53:21
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered empty.	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:16:19

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:59:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:10
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:52:38
User entered 'No (N)'	Flo Abbott (b) (4) (b) (4)	19 Oct 2020 17:16:19

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:59:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:10
User entered empty.	System	19 Oct 2020 17:16:19

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:59:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:10
User entered empty.	System	19 Oct 2020 17:16:19

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:59:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:10
User entered empty.	System	19 Oct 2020 17:16:19

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:59:26

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:14
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: SYMPATHOMIMETICS, PLAIN, PRODUCT: OXYMETAZOLINE HYDROCHLORIDE, PRODUCTSYNONYM: ZICAM [OXYMETAZOLINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 03:16:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 03:16:08
Data point term sent to Coder	System	06 Nov 2020 13:16:19
Coding entries removed.	Ayssa Valente (b) (4)	06 Nov 2020 13:16:15
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:48:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: SYMPATHOMIMETICS, PLAIN, PRODUCT: OXYMETAZOLINE HYDROCHLORIDE, PRODUCTSYNONYM: ZICAM [OXYMETAZOLINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 15:10:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 15:10:20
Data point term sent to Coder	System	02 Nov 2020 19:49:19
User closed query 'For coding purposes, references indicate different formulations for ZICAM . Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	System	02 Nov 2020 19:48:31

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:59:26

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'For coding purposes, references indicate different formulations for ZICAM . Please provide generic ingredients, complete, accurate trade name and update the term with your response' answered with 'updated to include generic name' (Site from System).	Brandy Lowman (b) (4)	02 Nov 2020 19:48:31
User entered 'ZICAM [oxymetazoline hydrochloride]' reason for change: Data Entry Error	(b) (4)	02 Nov 2020 19:48:19
User opened query 'For coding purposes, references indicate different formulations for ZICAM . Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	Coder Import (b) (4)	01 Nov 2020 13:59:45
Data point term sent to Coder	System	23 Oct 2020 15:18:21
User entered 'zicam'	Morgan Mathis (b) (4)	23 Oct 2020 15:18:14
	(b) (4)	

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:59:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:14
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:14

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:59:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:14
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 21:01:03
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:29:01
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Updated indication for use' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	06 Nov 2020 13:16:28
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	06 Nov 2020 13:16:15
User entered 'COVID-19 symptom relief' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	06 Nov 2020 13:16:15
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:40:17
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered 'convalescent visit'	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:14

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:59:26**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:14
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered 'l'	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:14

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:59:26**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:14
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered 'tablet (TABLET)'	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:14

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:59:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:14
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered empty.	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:14

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:59:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:14
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered 'once daily (QD)'	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:14

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:59:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:14
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered empty.	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:14

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:59:26**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:14
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered 'Oral (ORAL)'	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:14

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:59:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:14
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered empty.	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:14

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:14
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered '16 Oct 2020'	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:14

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:59:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:14
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered '0'	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:14

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:59:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:14
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:14

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:59:26**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:14
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered '22 Oct 2020'	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:14

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:59:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:14
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:14

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:59:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:14
User entered '1'	System	23 Oct 2020 15:18:14

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:59:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:14
User entered '1'	System	23 Oct 2020 15:18:14

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:59:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:53:14
User entered '804 (804)'	System	23 Oct 2020 15:18:14

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:59:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:07:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 13:30:33
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 13:30:33
Data point term sent to Coder	System	06 Nov 2020 13:14:18
Coding entries removed.	Ayssa Valente (b) (4)	06 Nov 2020 13:13:47
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:48:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 05:52:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 05:52:24
Data point term sent to Coder	System	23 Oct 2020 15:19:28
User entered 'vitamin c'	(b) (4), (b) (6)	23 Oct 2020 15:18:56

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:59:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:07:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 12:36:04
DataPoint Un-verified.	Brandy Lowman (b) (4)	09 Nov 2020 14:24:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Brandy Lowman (b) (4)	09 Nov 2020 14:24:28
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered 'No (N)'	Morgan Mathis (b) (4)	23 Oct 2020 15:18:56

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:59:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:07:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
User closed query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:49:56
Query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate' answered with 'prophylaxis updated to yes. ' (Site from DM).	Brandy Lowman (b) (4) (b) (4)	09 Nov 2020 14:24:43
User opened query 'Per DM CLR: Indication = NUTRITIONAL SUPPLEMENT. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 21:05:51
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:29:01
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Updated indication for use' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	06 Nov 2020 13:14:00
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	06 Nov 2020 13:13:47
User entered 'Nutritional supplement' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	06 Nov 2020 13:13:47

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:59:26

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 10:40:58
	(b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered 'convalescent visit'	Morgan Mathis (b) (4)	23 Oct 2020 15:18:56
	(b) (4)	

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:59:26**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:07:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered '1000'	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:56

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:59:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:07:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered 'mg (mg)'	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:56

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:59:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:07:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered empty.	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:56

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:59:26**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:07:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered 'once daily (QD)'	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:56

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:59:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:07:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered empty.	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:56

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:59:26**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:07:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered 'Oral (ORAL)'	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:56

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:59:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:07:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered empty.	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:56

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:59:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:07:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered '16 Oct 2020'	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:56

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:59:26**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:07:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered '0'	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:56

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:59:26**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:07:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:56

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:07:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered '22 Oct 2020'	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:56

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:59:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:07:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:48:40
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 15:18:56

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:59:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:07:59
User entered '1'	System	23 Oct 2020 15:18:56

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:59:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:07:59
User entered '1'	System	23 Oct 2020 15:18:56

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:59:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:07:59
User entered '804 (804)'	System	23 Oct 2020 15:18:56

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:59:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:08:42
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:02
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) (b) (4)	16 Nov 2020 03:40:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 03:40:51
Data point term sent to Coder	System	11 Nov 2020 16:55:54
User entered 'INFLUENZA VACCINE'	(b) (4), (b) (6)	11 Nov 2020 16:55:40

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:59:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:08:42
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:55:40

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:59:26**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:08:42
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:02
User entered 'ANNUAL FLU PREVENTATIVE'	(b) (4), (b) (6)	11 Nov 2020 16:55:40

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:59:26**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:08:42
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:02
User entered '0.5'	(b) (4), (b) (6)	11 Nov 2020 16:55:40

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:59:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:08:42
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:02
User entered 'mL (mL)'	(b) (4), (b) (6)	11 Nov 2020 16:55:40

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:59:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:08:42
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:02
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:55:40

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:59:26**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:08:42
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:02
User entered 'once (ONCE)'	(b) (4), (b) (6)	11 Nov 2020 16:55:40

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:59:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:08:42
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:02
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:55:40

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:59:26**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:08:42
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:02
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	11 Nov 2020 16:55:40

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:59:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:08:42
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:02
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:55:40

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:59:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:08:42
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	14 Dec 2020 20:14:17
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 19:50:20
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:02
User entered '29 Oct 2020'	(b) (4), (b) (6)	11 Nov 2020 16:55:40

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:59:26**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:08:42
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:02
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:55:40

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:59:26**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:08:42
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:02
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:55:40

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:59:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:08:42
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	14 Dec 2020 20:14:17
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 19:50:20
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 18:00:02
User entered '29 Oct 2020'	(b) (4), (b) (6)	11 Nov 2020 16:55:40

US3082247

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:59:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:08:42
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 19:14:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:00:02
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:55:40

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:59:26**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:08:42
User entered empty.	System	11 Nov 2020 16:55:40

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:59:26**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:08:42
User entered empty.	System	11 Nov 2020 16:55:40

**US3082247**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 21:59:26**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:08:42
User entered empty.	System	11 Nov 2020 16:55:40

US3082247

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 21:59:26

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 13:56:07
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered 'No (N)'	(b) (4) Ayssa Valente (b) (4) (b) (4)	03 Mar 2021 16:11:48

US3082247

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:59:26

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:19:34
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:11:49
User closed query 'Per source subject received positive illness result on 17Oct2021. As the positive result is the trigger for dosing discontinuation please update the date or provide clarification. ' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 14:11:23
Query 'Per source subject received positive illness result on 17Oct2021. As the positive result is the trigger for dosing discontinuation please update the date or provide clarification. ' answered with 'updated' (Site from CRA).	Erin Harrelson (b) (4) (b) (4)	08 Apr 2021 15:08:03
Signature has been broken.	Erin Harrelson (b) (4) (b) (4)	08 Apr 2021 15:07:31
User entered '17 Oct 2020' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	08 Apr 2021 15:07:31
User opened query 'Per source subject received positive illness result on 17Oct2021. As the positive result is the trigger for dosing discontinuation please update the date or provide clarification. ' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 14:11:21
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:58:34
User entered '26 Oct 2020'	Morgan Mathis (b) (4) (b) (4)	06 Nov 2020 17:56:17

US3082247

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:59:26

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:19:34
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:37
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4)	
reason for change: Data Entry Error	Ayssa Valente (b) (4)	12 Nov 2020 12:50:01
User entered 'SAE (specify) (SAE)' reason for	(b) (4)	
change: Data Entry Error	Morgan Mathis (b) (4)	06 Nov 2020 17:59:53
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4)	
	Morgan Mathis (b) (4)	06 Nov 2020 17:56:17
	(b) (4)	

US3082247

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:19:34
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:11:45
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User closed query 'Per CDM: Please review and verify if the Primary reason for dosing discontinuation could be recorded as "Due to SARS-COV-2" from the dropdown list provided as per page 42 of CCGs v2.0. Kindly update as appropriate, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:20:27
Query 'Per CDM: Please review and verify if the Primary reason for dosing discontinuation could be recorded as "Due to SARS-COV-2" from the dropdown list provided as per page 42 of CCGs v2.0. Kindly update as appropriate, else clarify. ' answered with 'primary reason for discontinuation updated to option from list' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	12 Nov 2020 12:50:37
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	12 Nov 2020 12:50:13
User entered empty; reason for change Data Entry Error	Ayssa Valente (b) (4) (b) (4)	12 Nov 2020 12:50:13
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	12 Nov 2020 12:50:01
User opened query 'Per CDM: Please review and verify if the Primary reason for dosing discontinuation could be recorded as "Due to SARS-COV-2" from the dropdown list provided as per page 42 of CCGs v2.0. Kindly update as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 08:37:12

US3082247

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Please note that per eCCGs if a participant received the first dose, but does not receive second dose at Visit 2 forms should still be completed under the Visit 2 Day 29 Folder. Please reconcile and update.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 13:02:01
Query 'Per CDM: Please note that per eCCGs if a participant received the first dose, but does not receive second dose at Visit 2 forms should still be completed under the Visit 2 Day 29 Folder. Please reconcile and update.' answered with 'updated. ' (Site from DM).	Morgan Mathis (b) (4)	09 Nov 2020 14:45:46
User opened query 'Per CDM: Please note that per eCCGs if a participant received the first dose, but does not receive second dose at Visit 2 forms should still be completed under the Visit 2 Day 29 Folder. Please reconcile and update.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:19:53
User entered 'THE PATIENT NOTIFIED THE SITE THAT SHE WAS EXPERIENCING SYMPTOMS OF COVID ON THE DAY THAT SHE WAS SUPPOSED TO GET HER SECOND DOSE. SITE TESTED HER FOR COVID AND SHE TESTED POSITIVE.' reason for change: Data Entry Error	Morgan Mathis (b) (4)	06 Nov 2020 18:00:17
User entered 'The patient notified the site that she was experiencing symptoms of COVID on the day that she was supposed to get her second dose. Site tested her for COVID.' reason for change: Data Entry Error	Morgan Mathis (b) (4)	06 Nov 2020 17:59:53
User entered empty.	Morgan Mathis (b) (4)	06 Nov 2020 17:56:17

US3082247

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:59:26

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:19:34
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:13:30
Signature has been broken.	Angie Northcott (b) (4)	15 Mar 2021 18:11:33
User entered '15 Mar 2021' reason for change: Data Entry Error	Angie Northcott (b) (4)	15 Mar 2021 18:11:33
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 09:23:07
Query 'Data is required. Please complete.' answered with 'subject not discontinued from study. Only discontinued from drug. ' (Site from System).	Erin Harrelson (b) (4)	14 Dec 2020 20:15:03
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	14 Dec 2020 20:14:17
User entered '26 Oct 2020'	Erin Harrelson (b) (4)	14 Dec 2020 20:14:17
	(b) (4)	
	Morgan Mathis (b) (4)	14 Dec 2020 19:50:20
	(b) (4)	

US3082247

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:59:26

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:19:34
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:34:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:13:47
Signature has been broken.	Angie Northcott (b) (4)	15 Mar 2021 18:11:33
User entered 'Lost To Follow-up (LOST TO FOLLOW-UP)' reason for change: Data Entry Error	Angie Northcott (b) (4)	15 Mar 2021 18:11:33
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 09:23:09
Query 'Data is required. Please complete.' answered with 'Subject not discontinued from study, only from drug. ' (Site from System).	Erin Harrelson (b) (4)	14 Dec 2020 20:15:24
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	14 Dec 2020 20:14:17
User entered 'AE (specify) (ADVERSE EVENT)'	Erin Harrelson (b) (4)	14 Dec 2020 20:14:17
	(b) (4)	
	Morgan Mathis (b) (4)	14 Dec 2020 19:50:20
	(b) (4)	

US3082247

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:59:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:19:34
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:13:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty; reason for change Data Entry Error	(b) (4)	
	Erin Harrelson (b) (4)	14 Dec 2020 20:14:17
	(b) (4)	
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	14 Dec 2020 19:51:19
User entered 'Patient got the COVID-19 infection.' reason for change: Data Entry Error	Morgan Mathis (b) (4)	14 Dec 2020 19:51:19
	(b) (4)	
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	14 Dec 2020 19:50:20
User entered empty.	Morgan Mathis (b) (4)	14 Dec 2020 19:50:20
	(b) (4)	

US3082247

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:59:26

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:19:34
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:13:51
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Morgan Mathis (b) (4) (b) (4)	14 Dec 2020 19:50:20

US3082247

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:59:26

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:19:34
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:13:53
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Morgan Mathis (b) (4) (b) (4)	14 Dec 2020 19:50:20

US3082247

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:59:26

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:19:34
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:13:55
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Morgan Mathis (b) (4) (b) (4)	14 Dec 2020 19:50:20

US3082247

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:59:26

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:19:34
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:13:57
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered empty.	(b) (4) Morgan Mathis (b) (4)	14 Dec 2020 19:50:20

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'USA-US114-2020-MRNA-1273-P301000005'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'Barton'	System	19 Oct 2020 12:21:30

US3082247

Folder: SAE USA-US114-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:59:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'Williams'	System	19 Oct 2020 12:21:30

US3082247

Folder: SAE USA-US114-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:59:26

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:55:46
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:48:30
Un-reviewed for Safety.	System	21 Oct 2020 16:42:30
User entered '3806 Peachtree Ave.'	System	21 Oct 2020 16:42:30
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 16:42:18
Un-reviewed for Safety.	Flo Abbott (b) (4)	19 Oct 2020 17:06:17
User entered '1221 Floral Parkway, Suite 101'	(b) (4)	19 Oct 2020 17:06:17
reason for change: Data Entry Error	Flo Abbott (b) (4)	19 Oct 2020 17:06:17
Reviewed for Safety.	(b) (4)	19 Oct 2020 16:36:30
User entered '3806 Peachtree Ave.'	(b) (4), (b) (6)	19 Oct 2020 16:36:30
	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'Wilmington'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'NC'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered '28403'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:53
User entered 'US'	System	19 Oct 2020 16:36:38

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User entered '4'	System	15 Dec 2020 14:55:59
User entered '3'	System	07 Nov 2020 01:25:21
User entered '2'	System	21 Oct 2020 16:42:30
User entered '1'	System	19 Oct 2020 16:36:38

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'USA-US114-2020-MRNA-1273-P301000005'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'Barton'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'Williams'	System	19 Oct 2020 12:21:30

US3082247

Folder: SAE USA-US114-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:59:26

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:55:46
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:48:30
Un-reviewed for Safety.	System	21 Oct 2020 16:42:30
User entered '3806 Peachtree Ave.'	System	21 Oct 2020 16:42:30
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 16:42:18
Un-reviewed for Safety.	Flo Abbott (b) (4)	19 Oct 2020 17:06:17
User entered '1221 Floral Parkway, Suite 101'	(b) (4)	19 Oct 2020 17:06:17
reason for change: Data Entry Error	Flo Abbott (b) (4)	19 Oct 2020 17:06:17
Reviewed for Safety.	(b) (4)	19 Oct 2020 16:36:30
User entered '3806 Peachtree Ave.'	(b) (4), (b) (6)	19 Oct 2020 16:36:30
	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'Wilmington'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'NC'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered '28403'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:53
User entered 'US'	System	19 Oct 2020 16:36:38

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User entered '4'	System	15 Dec 2020 14:55:59
User entered '3'	System	07 Nov 2020 01:25:21
User entered '2'	System	21 Oct 2020 16:42:30
User entered '1'	System	19 Oct 2020 16:36:38

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (1)**

**Generated On: 11 Aug 2021 21:59:26**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
User entered '19/Oct/2020 16:36'	System	19 Oct 2020 16:36:38

US3082247

Folder: SAE USA-US114-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:59:26

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:53
User entered 'I'	(b) (4), (b) (6)	19 Oct 2020 16:36:38

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'USA-US114-2020-MRNA-1273-P301000005'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'Barton'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'Williams'	System	19 Oct 2020 12:21:30

US3082247

Folder: SAE USA-US114-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:59:26

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:55:46
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:48:30
Un-reviewed for Safety.	System	21 Oct 2020 16:42:30
User entered '3806 Peachtree Ave.'	System	21 Oct 2020 16:42:30
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 16:42:18
Un-reviewed for Safety.	Flo Abbott (b) (4)	19 Oct 2020 17:06:17
User entered '1221 Floral Parkway, Suite 101'	(b) (4)	19 Oct 2020 17:06:17
reason for change: Data Entry Error	Flo Abbott (b) (4)	19 Oct 2020 17:06:17
Reviewed for Safety.	(b) (4)	19 Oct 2020 16:36:30
User entered '3806 Peachtree Ave.'	(b) (4), (b) (6)	19 Oct 2020 16:36:30
	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'Wilmington'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'NC'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered '28403'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:53
User entered 'US'	System	19 Oct 2020 16:36:38

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User entered '4'	System	15 Dec 2020 14:55:59
User entered '3'	System	07 Nov 2020 01:25:21
User entered '2'	System	21 Oct 2020 16:42:30
User entered '1'	System	19 Oct 2020 16:36:38

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (2)**

**Generated On: 11 Aug 2021 21:59:26**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
User entered '21/Oct/2020 16:42'	System	21 Oct 2020 16:42:30

US3082247

Folder: SAE USA-US114-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:59:26

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:55:46
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:48:30
User entered 'I'	(b) (4), (b) (6)	21 Oct 2020 16:42:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'USA-US114-2020-MRNA-1273-P301000005'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'Barton'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'Williams'	System	19 Oct 2020 12:21:30

US3082247

Folder: SAE USA-US114-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:59:26

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:55:46
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:48:30
Un-reviewed for Safety.	System	21 Oct 2020 16:42:30
User entered '3806 Peachtree Ave.'	System	21 Oct 2020 16:42:30
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 16:42:18
Un-reviewed for Safety.	Flo Abbott (b) (4)	19 Oct 2020 17:06:17
User entered '1221 Floral Parkway, Suite 101'	(b) (4)	19 Oct 2020 17:06:17
reason for change: Data Entry Error	Flo Abbott (b) (4)	19 Oct 2020 17:06:17
Reviewed for Safety.	(b) (4)	19 Oct 2020 16:36:30
User entered '3806 Peachtree Ave.'	(b) (4), (b) (6)	19 Oct 2020 16:36:30
	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'Wilmington'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'NC'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered '28403'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:53
User entered 'US'	System	19 Oct 2020 16:36:38

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User entered '4'	System	15 Dec 2020 14:55:59
User entered '3'	System	07 Nov 2020 01:25:21
User entered '2'	System	21 Oct 2020 16:42:30
User entered '1'	System	19 Oct 2020 16:36:38

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (3)**

**Generated On: 11 Aug 2021 21:59:26**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:59:41
User entered '06/Nov/2020 20:25'	System	07 Nov 2020 01:25:21

US3082247

Folder: SAE USA-US114-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:59:26

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:55:46
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 17:59:41
User entered 'I'	(b) (4), (b) (6)	07 Nov 2020 01:25:21

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'USA-US114-2020-MRNA-1273-P301000005'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

US3082247

Folder: SAE USA-US114-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:59:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'No (N)'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'Barton'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'Williams'	System	19 Oct 2020 12:21:30

US3082247

Folder: SAE USA-US114-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:59:26

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:55:46
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:48:30
Un-reviewed for Safety.	System	21 Oct 2020 16:42:30
User entered '3806 Peachtree Ave.'	System	21 Oct 2020 16:42:30
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 16:42:18
Un-reviewed for Safety.	Flo Abbott (b) (4)	19 Oct 2020 17:06:17
User entered '1221 Floral Parkway, Suite 101'	(b) (4)	19 Oct 2020 17:06:17
reason for change: Data Entry Error	Flo Abbott (b) (4)	19 Oct 2020 17:06:17
Reviewed for Safety.	(b) (4)	19 Oct 2020 16:36:30
User entered '3806 Peachtree Ave.'	(b) (4), (b) (6)	19 Oct 2020 16:36:30
	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'Wilmington'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered 'NC'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:30
User entered '28403'	System	19 Oct 2020 12:21:30

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:48:30
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:36:53
User entered 'US'	System	19 Oct 2020 16:36:38

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:59:26**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
User entered '4'	System	15 Dec 2020 14:55:59
User entered '3'	System	07 Nov 2020 01:25:21
User entered '2'	System	21 Oct 2020 16:42:30
User entered '1'	System	19 Oct 2020 16:36:38

**US3082247**

**Folder: SAE USA-US114-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (4)**

**Generated On: 11 Aug 2021 21:59:26**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 13:34:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered '15/Dec/2020 06:55'	(b) (4) System	15 Dec 2020 14:55:59

US3082247

Folder: SAE USA-US114-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 21:59:26

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:13:03
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 13:34:40
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:58:34
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:55:59