

US3082221 (Prod: Trial Management Associates LLC - ERN - PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:57:46

All time stamps listed in this document are displayed in GMT

US3082221

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 16:33:40

Generated On: 11 Aug 2021 21:57:46

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Participant ID

US3082221

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

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US3082221

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3082221

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Date of Birth (MMM yyyy)	(b) (6) 1984
Age	36
Age Units	YEARS
Age (Derived)	36
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

US3082221

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Date of Informed Consent (dd MMM yyyy) 10 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

US3082221

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 18:53:23

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3082221

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 18:53:23

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 18:53:23

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Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 18:53:23

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	10 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	08:29 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 08:29
Height ( <i>xxx.x</i> )	65.5 in
Weight ( <i>xxx.x</i> )	176.5 lb
BMI ( <i>xxx.x</i> )	28.98491 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)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:53:23

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 18:53:23

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Date of assessment (dd MMM yyyy) 10 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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 18:53:23

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Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	10 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)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 18:53:23

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**Occupational Risk**

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☒ No ☐

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

**Warehouse shipping and fulfillment centers** and jobs (e.g., Amazon facilities) Yes ☐ No ☒

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 18:53:23

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

What was the date of randomization? (dd MMM yyyy) 10 SEP 2020

What was the participant's randomization number? 112719

In what Cohort was the participant enrolled?   
 >=18 and <65 years and not at risk ☒   
 >=18 and <65 years and at risk ☐   
 >=65 years ☐

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

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

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)	10 SEP 2020
Time of assessment (00:00-23:59)	08:29 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 08:29
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

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)	10 SEP 2020
Time of assessment (00:00-23:59)	09:42 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 09:42
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	68 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)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

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

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

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 09:10 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 09:10

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 SEP 2020

Collection time (00:00-23:59)

08:35 (24 HR)

Collection date and time (derived)

10 SEP 2020 08:35

US3082221

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:39	10 SEP 2020 08:39
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

**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

98.1 °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

10 SEP 2020 09:46

PC Open Date & Time

10 SEP 2020 09:30

PC Close Date & Time

10 SEP 2020 12:00

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °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	10 SEP 2020 21:55
PC Open Date & Time	10 SEP 2020 12:55
PC Close Date & Time	11 SEP 2020 11:59

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

11 SEP 2020 19:29

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:46

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

13 SEP 2020 10:34

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:46

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

13 SEP 2020 23:59

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:46

**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

98.2 °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

15 SEP 2020 06:21

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:46

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**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

98.0 °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

15 SEP 2020 20:10

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59



US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:46

**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

16 SEP 2020 19:19

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

**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

10 SEP 2020 09:47

PC Open Date & Time

10 SEP 2020 09:30

PC Close Date & Time

10 SEP 2020 12:00

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 21:55

PC Open Date & Time

10 SEP 2020 12:55

PC Close Date & Time

11 SEP 2020 11:59

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:46

**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

11 SEP 2020 19:29

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 10:34

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:46

**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

13 SEP 2020 23:59

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:46

**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

15 SEP 2020 06:21

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:46

**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

15 SEP 2020 20:10

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59



US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:46

**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

16 SEP 2020 19:19

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

**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 ☐

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 09:47
PC Open Date & Time	10 SEP 2020 09:30
PC Close Date & Time	10 SEP 2020 12:00

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

**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 ☐

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 21:56
PC Open Date & Time	10 SEP 2020 12:55
PC Close Date & Time	11 SEP 2020 11:59

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:46

**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 ☒

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:46

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 19:30
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:46

		Yes <input type="checkbox"/>
PC Time stamp	13 SEP 2020 10:35	
PC Open Date & Time	12 SEP 2020 12:00	
PC Close Date & Time	13 SEP 2020 11:59	

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:46

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 ☒

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:46

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 00:00
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:46

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 ☒

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:46

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 06:21
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:46

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 ☒

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:46

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 20:10
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:46

**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 ☒



US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:46

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 19:19
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3082221

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:33:44

Generated On: 11 Aug 2021 21:57:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3082221

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:33:44

Generated On: 11 Aug 2021 21:57:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082221

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3082221

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082221

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3082221

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082221

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2



US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

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)	13 OCT 2020
Time of assessment (00:00-23:59)	11:03 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 11:03
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

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)	13 OCT 2020
Time of assessment (00:00-23:59)	12:18 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 12:18
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3082221

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3082221

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	13 OCT 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)	

US3082221

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

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) 13 OCT 2020

What was the treatment time? (00:00-23:59) 11:48 (24 HR)

Treatment Date and Time (derived) 13 OCT 2020 11:48

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

US3082221

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

11:20 (24 HR)

Collection date and time (derived)

13 OCT 2020 11:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Collection date (dd MMM yyyy)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:22	13 OCT 2020 11:22
Nasopharyngeal Swab 2	No		

US3082221

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 12:18

PC Open Date & Time

13 OCT 2020 12:08

PC Close Date & Time

13 OCT 2020 14:38

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.1 °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	13 OCT 2020 20:55
PC Open Date & Time	13 OCT 2020 15:33
PC Close Date & Time	14 OCT 2020 11:59

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 05:18

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 22:03

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:46

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**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

97.1 °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

17 OCT 2020 09:21

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 22:11

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 22:08

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:46

**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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 21:18

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59



US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

**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

13 OCT 2020 12:18

PC Open Date & Time

13 OCT 2020 12:08

PC Close Date & Time

13 OCT 2020 14:38

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 20:55

PC Open Date & Time

13 OCT 2020 15:33

PC Close Date & Time

14 OCT 2020 11:59

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:46

**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

15 OCT 2020 05:18

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 22:03

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:46

**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

17 OCT 2020 09:21

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:46

**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

17 OCT 2020 22:11

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:46

**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

18 OCT 2020 22:07

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:46

**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

19 OCT 2020 21:19

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59



US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

**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 ☐

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 12:19
PC Open Date & Time	13 OCT 2020 12:08
PC Close Date & Time	13 OCT 2020 14:38

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

**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 ☐

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 20:55
PC Open Date & Time	13 OCT 2020 15:33
PC Close Date & Time	14 OCT 2020 11:59

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:46

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 05:18
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:46

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 ☒

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:46

		Yes <input type="checkbox"/>
PC Time stamp	15 OCT 2020 22:04	
PC Open Date & Time	15 OCT 2020 12:00	
PC Close Date & Time	16 OCT 2020 11:59	



US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:46

**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 ☒

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:46

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 09:21
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:46

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 ☒

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:46

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 22:11
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:46

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 ☒

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:46

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 22:08
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:46

**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 ☒

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:46

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 21:19
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59



US3082221

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3082221

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082221

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3082221

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082221

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:33:44

Generated On: 11 Aug 2021 21:57:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3082221

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:33:44

Generated On: 11 Aug 2021 21:57:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082221

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:53:45

Generated On: 11 Aug 2021 21:57:46

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	VISIT3

US3082221

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 18:53:45

Generated On: 11 Aug 2021 21:57:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	11 NOV 2020
Time of assessment ( <i>00:00-23:59</i> )	11:06 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 11:06
Temperature ( <i>xxx.x</i> )	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	86 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3082221

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:53:45

Generated On: 11 Aug 2021 21:57:46

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.*

US3082221

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:53:45

Generated On: 11 Aug 2021 21:57:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	11 NOV 2020
-------------------------------	-------------

Collection time (00:00-23:59)	11:27 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	11 NOV 2020 11:27
------------------------------------	-------------------

US3082221

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:53:45

Generated On: 11 Aug 2021 21:57:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 11:29:58
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3082221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 71

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

No ☒

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 11:38:21

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

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	24 NOV 2020 06:27:01
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

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 <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	28 NOV 2020 10:02:18
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

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 <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	07 DEC 2020 12:05:00
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59



US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

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	12 DEC 2020 06:24:05
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 09:13:06

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**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

29 DEC 2020 17:59:38

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 05:46:19
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

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	10 JAN 2021 21:39:12
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 14:40:06

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**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

25 JAN 2021 12:33:46

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**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

02 FEB 2021 21:08:42

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59



US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**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

07 FEB 2021 22:41:33

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 12:55:51

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 14:11:19

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**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

01 MAR 2021 15:29:32

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 MAR 2021 22:31:56
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	15 MAR 2021 12:46:33
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 06:31:48

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 06:28:47

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59



US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 10:12:56

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 APR 2021 18:06:09

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 06:33:25

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 12:01:39

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAY 2021 12:51:13
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 250

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>



**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Please 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](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2021 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 341

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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14 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 AUG 2021 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 SEP 2021 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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02 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 OCT 2021 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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09 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2021 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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16 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 OCT 2021 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 411

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

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

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

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

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

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

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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20 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 NOV 2021 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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04 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 DEC 2021 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 460

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

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

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

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

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

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

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59
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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JAN 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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



**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 FEB 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

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23 MAR 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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26 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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23 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 APR 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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02 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUL 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

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

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



**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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16 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUL 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Please 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](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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13 AUG 2022 00:01

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17 AUG 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Please 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 AUG 2022 00:01

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24 AUG 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2022 00:01

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31 AUG 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

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03 SEP 2022 00:01

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07 SEP 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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10 SEP 2022 00:01

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14 SEP 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

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21 SEP 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

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28 SEP 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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01 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 OCT 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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08 OCT 2022 00:01

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12 OCT 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

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19 OCT 2022 23:59

US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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22 OCT 2022 00:01

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26 OCT 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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



**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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29 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

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

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[Patient Cloud Open Date & Time](#)

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05 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 NOV 2022 23:59

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US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3082221**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Please 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"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 NOV 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 NOV 2022 23:59

US3082221

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 21:57:46

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 15:29:41

US3082221

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:33:44

Generated On: 11 Aug 2021 21:57:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3082221

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:33:44

Generated On: 11 Aug 2021 21:57:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3082221

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:33:44

Generated On: 11 Aug 2021 21:57:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3082221

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:33:43

Generated On: 11 Aug 2021 21:57:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082221

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:33:44

Generated On: 11 Aug 2021 21:57:46

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*

US3082221

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:33:44

Generated On: 11 Aug 2021 21:57:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082221

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 12:31:54

Generated On: 11 Aug 2021 21:57:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3082221

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 12:31:54

Generated On: 11 Aug 2021 21:57:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082221

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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

Visit date (dd MMM yyyy)	23 APR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3082221

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

Were vital signs assessed? Yes ☐  
No ☒

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

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

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

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_



US3082221

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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.*

US3082221

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 APR 2021

Collection time (00:00-23:59)

11:17 (24 HR)

Collection date and time (derived)

23 APR 2021 11:17

US3082221

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3082221**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3082221**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 05 Mar 2021 16:33:40

Generated On: 11 Aug 2021 21:57:46

Date of Contact	13 JAN 2021
Time of Contact	00:00
Date and Time of Contact (derived)	13 JAN 2021 00:00
Type of Contact	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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	1 JAN 2021	
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)

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US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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"/>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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"/>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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 type="checkbox"/>
Day 15	<input checked="" 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"/>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	98.7 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"/>



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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 type="radio"/>
	Mild	<input checked="" 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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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 type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.3 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"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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

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Form: Symptom Log (4)

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Generated On: 11 Aug 2021 21:57:46

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 type="radio"/>
	Mild	<input checked="" 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"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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 type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input checked="" type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.4 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 22:02:42

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

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Form: Symptom Log (5)

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Generated On: 11 Aug 2021 21:57:46

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 type="radio"/>
	Mild	<input checked="" 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"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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 type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

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

Temperature	96 F
-------------	------

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

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

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

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

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Form: Symptom Log (6)

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Generated On: 11 Aug 2021 21:57:46

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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 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 checked="" type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	96.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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 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 checked="" type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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 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 checked="" type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	96.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>



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Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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 type="radio"/>
	Mild	<input checked="" 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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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 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 checked="" type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	96.9 F
-------------	--------

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

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

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

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

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Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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 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 checked="" type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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"/>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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 ☐

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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 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 checked="" type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	97.9 F
-------------	--------

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

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

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

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

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Generated On: 11 Aug 2021 21:57:46

	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"/>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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 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 checked="" 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"/>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	96.1 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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 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 checked="" type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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 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 checked="" type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

Symptom Day

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

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Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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	2 JAN 2021	
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"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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	3 JAN 2021	
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"/>



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Form: Symptom Log (17)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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"/>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

Symptom Day

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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	4 JAN 2021	
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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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	5 JAN 2021	
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"/>

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EAB) (1725)

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Form: Symptom Log (19)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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	6 JAN 2021	
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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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	7 JAN 2021	
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"/>



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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	8 JAN 2021	
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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (23)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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	9 JAN 2021	
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"/>

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Form: Symptom Log (23)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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	10 JAN 2021
------	-------------

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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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	11 JAN 2021	
Assessment Not Done	True	
O2 Saturation	<hr/>	
O2 Saturation Units	<hr/>	
Temperature	<hr/>	
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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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	12 JAN 2021	
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"/>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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"/>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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 JAN 2021	
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)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

	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)

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US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Data signed: (b) (4) 28 Apr 2021 22:02:42

Generated On: 11 Aug 2021 21:57:46

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"/>

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Apr 2021 12:31:54

Generated On: 11 Aug 2021 21:57:46

Date of Visit	14 JAN 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	14 JAN 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 12:31:54

Generated On: 11 Aug 2021 21:57:46

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 15 JAN 2021

End Date 15 JAN 2021

Oxygen Saturation 93 %

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 \_\_\_\_\_

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 12:31:54

Generated On: 11 Aug 2021 21:57:46

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

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 12:31:54

Generated On: 11 Aug 2021 21:57:46

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

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 05 Mar 2021 16:33:40

Generated On: 11 Aug 2021 21:57:46

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[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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US3082221

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 19 Feb 2021 18:53:23

Generated On: 11 Aug 2021 21:57:46

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	16 JAN 2021
Day 5	Yes	18 JAN 2021
Day 7	Yes	20 JAN 2021
Day 9	Yes	22 JAN 2021
Day 14	Yes	27 JAN 2021
Day 21	Yes	03 FEB 2021
Day 28	Yes	11 FEB 2021



US3082221

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:33:43

Generated On: 11 Aug 2021 21:57:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	14 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>

Folder OID	SICKD1
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US3082221

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 16:33:43

Generated On: 11 Aug 2021 21:57:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	00:00 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 00:00
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3082221

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 16:33:43

Generated On: 11 Aug 2021 21:57:46

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.*

US3082221

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 16:33:43

Generated On: 11 Aug 2021 21:57:46

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

14 JAN 2021

US3082221

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:53:22

Generated On: 11 Aug 2021 21:57:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3082221

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 18:53:22

Generated On: 11 Aug 2021 21:57:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	08:15 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 08:15
Height (xxx.x)	63.0 in
Weight (xxx.x)	167.8 lb
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3082221

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:53:22

Generated On: 11 Aug 2021 21:57:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 FEB 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3082221

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 18:53:22

Generated On: 11 Aug 2021 21:57:46

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

11 FEB 2021



US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:33:43

Generated On: 11 Aug 2021 21:57:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 12:31:54

Generated On: 11 Aug 2021 21:57:46

Date of updated informed consent ( <i>dd MMM yyyy</i> )	6 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	8 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 16:33:43

Generated On: 11 Aug 2021 21:57:46

Height	63.0 in
Weight	170.2 lb
BMI (xxx.x)	30.21262

US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 16:33:43

Generated On: 11 Aug 2021 21:57:46

Height	63.0 in
Weight	170.2 lb
BMI (xxx.x)	30.21262
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)	8 JAN 2021
Time of assessment (00:00-23:59)	11:33 (24 HR)
Vital Signs Date and Time (derived)	8 JAN 2021 11:33
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 16:33:43

Generated On: 11 Aug 2021 21:57:46

Height	63.0 in
Weight	170.2 lb
BMI (xxx.x)	30.21262
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)	8 JAN 2021
Time of assessment (00:00-23:59)	11:51 (24 HR)
Vital Signs Date and Time (derived)	8 JAN 2021 11:51
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 16:33:43

Generated On: 11 Aug 2021 21:57:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 JAN 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Data signed: (b) (4) 05 Mar 2021 16:33:43

Generated On: 11 Aug 2021 21:57:46

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	8 JAN 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 16:33:43

Generated On: 11 Aug 2021 21:57:46

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 8 JAN 2021

What was the treatment time? (00:00-23:59) 12:20 (24 HR)

Treatment Date and Time (derived) 8 JAN 2021 12:20

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



US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 16:33:43

Generated On: 11 Aug 2021 21:57:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 JAN 2021
Collection time (00:00-23:59)	11:55 (24 HR)
Collection date and time (derived)	8 JAN 2021 11:55

US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 16:33:43

Generated On: 11 Aug 2021 21:57:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 JAN 2021
Collection time (00:00 - 23:59)	11:53
Collection Date and Time (derived)	8 JAN 2021 11:53

US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:33:43

Generated On: 11 Aug 2021 21:57:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082221

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:33:44

Generated On: 11 Aug 2021 21:57:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3082221

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:33:44

Generated On: 11 Aug 2021 21:57:46

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3082221

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:33:43

Generated On: 11 Aug 2021 21:57:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3082221

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 16:33:43

Generated On: 11 Aug 2021 21:57:46

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)	11 FEB 2021
Time of assessment (00:00-23:59)	08:15 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 08:15
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3082221

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 16:33:43

Generated On: 11 Aug 2021 21:57:46

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)	11 FEB 2021
Time of assessment (00:00-23:59)	09:24 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 09:24
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)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG



US3082221

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 16:33:43

Generated On: 11 Aug 2021 21:57:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 FEB 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3082221

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 16 Apr 2021 12:31:54

Generated On: 11 Aug 2021 21:57:46

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	11 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3082221

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 16:33:43

Generated On: 11 Aug 2021 21:57:46

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 FEB 2021

What was the treatment time? (00:00-23:59) 08:54 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 08:54

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

US3082221

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:33:43

Generated On: 11 Aug 2021 21:57:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082221

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:33:44

Generated On: 11 Aug 2021 21:57:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3082221

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:33:44

Generated On: 11 Aug 2021 21:57:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3082221

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 12:31:54

Generated On: 11 Aug 2021 21:57:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3082221

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 12:31:54

Generated On: 11 Aug 2021 21:57:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 MAR 2021
Time of assessment (00:00-23:59)	09:09 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 09:09
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3082221

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 12:31:54

Generated On: 11 Aug 2021 21:57:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 MAR 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3082221

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 12:31:54

Generated On: 11 Aug 2021 21:57:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 MAR 2021

Collection time (00:00-23:59)

09:12 (24 HR)

Collection date and time (derived)

17 MAR 2021 09:12

US3082221

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 18:53:22

Generated On: 11 Aug 2021 21:57:46

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3082221

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 12:31:54

Generated On: 11 Aug 2021 21:57:46

AEID	USA-US114-2021-MRNA-1273-P30 1000003
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	1 JAN 2021
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 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 12:31:54

Generated On: 11 Aug 2021 21:57:46

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 18:53:22

Generated On: 11 Aug 2021 21:57:46

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 18:53:22

Generated On: 11 Aug 2021 21:57:46

Name of Medication MAGNESIUM

Prophylaxis Yes ☐  
No ☒

Indication SUPPLEMENT

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

TWICE WEEKLY

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 18:53:22

Generated On: 11 Aug 2021 21:57:46

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 18:53:22

Generated On: 11 Aug 2021 21:57:46

Name of Medication ZYRTEC (CETIRIZINE AND HYDROCHLORIDE)

Prophylaxis Yes ☐  
No ☒

Indication ALLERGIC RHINITIS

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 18:53:22

Generated On: 11 Aug 2021 21:57:46

	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)	UN UNK 2018	
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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 18:53:22

Generated On: 11 Aug 2021 21:57:46

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PROPHYLAXIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 18:53:22

Generated On: 11 Aug 2021 21:57:46

	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)		30 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)		30 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"/>

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 18:53:22

Generated On: 11 Aug 2021 21:57:46

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE R/T COVID-19

Dose per administration 800

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)

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US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 18:53:22

Generated On: 11 Aug 2021 21:57:46

	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)		15 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 15 JAN 2021		
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"/>

US3082221

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 16:33:40

Generated On: 11 Aug 2021 21:57:46

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3082221

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:57:46

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify



US3082221

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:57:46

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3082221

Folder: SAE USA-US114-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 12:31:54

Generated On: 11 Aug 2021 21:57:46

SAEID	USA-US114-2021-MRNA-1273-P301000003
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)	3

US3082221

Folder: SAE USA-US114-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 12:31:54

Generated On: 11 Aug 2021 21:57:46

SAEID	USA-US114-2021-MRNA-1273-P301000003
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)	3
Date of submission (Pre-filled from custom function)	19/JAN/2021 23:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3082221

Folder: SAE USA-US114-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 12:31:54

Generated On: 11 Aug 2021 21:57:46

SAEID	USA-US114-2021-MRNA-1273-P301000003
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)	3
Date of submission (Pre-filled from custom function)	02/FEB/2021 16:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3082221

Folder: SAE USA-US114-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 12:31:54

Generated On: 11 Aug 2021 21:57:46

SAEID	USA-US114-2021-MRNA-1273-P301000003
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)	3
Date of submission (Pre-filled from custom function)	30/MAR/2021 06:34
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

US3082221 (Prod: Trial Management Associates LLC - ERN - PPDS)

**US3082221**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 21:57:46**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:03:23
User entered 'US3082221'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Sep 2020 12:24:22

**US3082221**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:03:41
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:18:51



US3082221

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:57:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:03:41
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Sep 2020 12:24:23

**US3082221**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:03:41
User entered 'Clinic (Clinic)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:18:51

**US3082221**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User entered 'SCRN'	System	10 Sep 2020 13:18:51

US3082221

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:57:46

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:03:53
User entered (b) (6) 1984'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Sep 2020 12:24:24

**US3082221**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:46**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:03:53
User entered '36'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:19:37

**US3082221**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:46**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User entered 'YEARS'	System	10 Sep 2020 13:19:37

**US3082221**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:46**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User entered '36'	System	10 Sep 2020 13:20:26

US3082221

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:57:46

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:03:53
User entered 'Female (F)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:19:37



US3082221

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:57:46

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:03:53
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:19:37

**US3082221**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:46**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:03:53
User entered 'I'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:19:37

**US3082221**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:46**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:03:53
User entered '0'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:19:37

**US3082221**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:46**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:03:53
User entered '0'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:19:37

**US3082221**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:46**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:03:53
User entered '0'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:19:37

**US3082221**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:46**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:03:53
User entered '0'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:19:37

**US3082221**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:46**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:03:53
User entered '0'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:19:37

**US3082221**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:46**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:03:53
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:19:37



**US3082221**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:46**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:03:53
User entered '0'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:19:37

**US3082221**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:46**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:03:53
User entered '0'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:19:37

US3082221

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:57:46

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:04
User entered '10 Sep 2020' reason for change: Data Entry Error	Erin Harrelson (b) (4)	10 Sep 2020 13:25:00
User entered '10 Aug 2020'	(b) (4) Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:20:26

**US3082221**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:57:46**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User entered 'Sep 2020'	System	10 Sep 2020 13:25:00
User entered 'Aug 2020'	System	10 Sep 2020 13:20:26

**US3082221**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:57:46**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User entered '2020'	System	10 Sep 2020 13:20:26

**US3082221**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:57:46**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:04
User entered 'Amendment 3 (3)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:20:26

**US3082221**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:57:46**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:04
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:20:26

**US3082221**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:57:46**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:04
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:20:26



**US3082221**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:57:46**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:04
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:20:26

**US3082221**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:57:46**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:04
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:20:26

**US3082221**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:57:46**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:04
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Sep 2020 12:24:23

US3082221

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:57:46

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User entered 'I'	System	10 Sep 2020 13:20:29

**US3082221**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 11 Aug 2021 21:57:46**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:25
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:20:29

US3082221

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 21:57:46

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:58:40
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:20:57

US3082221

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:57:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:46
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 14:02:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 14:02:40
Data point term sent to Coder	System	10 Sep 2020 14:01:32
User entered 'Allergic Rhinitis'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 14:01:08

**US3082221**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:46
User entered 'UN UNK 2018'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 14:01:08



**US3082221**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:46
User entered '0'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 14:01:08

**US3082221**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:46
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 14:01:08

**US3082221**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:57:46**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:46
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 14:01:08

**US3082221**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:46
User entered '0'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 14:01:08

**US3082221**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User entered 'Jan 2018'	System	10 Sep 2020 14:01:08

**US3082221**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User entered '2018'	System	10 Sep 2020 14:01:08

**US3082221**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User entered empty.	System	10 Sep 2020 14:01:08

**US3082221**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User entered empty.	System	10 Sep 2020 14:01:08



**US3082221**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:55
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:23:36

**US3082221**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:55
User entered '10 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:23:36

**US3082221**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:55
User entered '08:29'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:23:36

**US3082221**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User entered '10 Sep 2020 08:29'	System	10 Sep 2020 13:23:36

US3082221

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:55
User entered '65.5' in	Erin Harrelson (b) (4)	10 Sep 2020 13:23:36
DataPoint set to visible.	(b) (4) System	10 Sep 2020 13:20:29

US3082221

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:55
User entered '176.5' lb	Erin Harrelson (b) (4)	10 Sep 2020 13:23:36
DataPoint set to visible.	(b) (4) System	10 Sep 2020 13:20:29

US3082221

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User entered '28.98491'	System	10 Sep 2020 13:23:36
DataPoint set to visible.	System	10 Sep 2020 13:20:29

**US3082221**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User entered 'kg/m2'	System	10 Sep 2020 13:23:36
DataPoint set to visible.	System	10 Sep 2020 13:20:29



US3082221

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:55
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 10:35:04
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' answered with 'COMPLETED.' (Site from DM).	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 14:08:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 14:07:55
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 05:10:36
User entered '98.0' F	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:23:36

US3082221

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:55
User entered empty; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 14:07:55
User entered 'Other (Other)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:23:36

US3082221

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:55
User entered empty; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 14:07:55
User entered 'forehead'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:23:36

**US3082221**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 14:07:55
User entered '66'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:23:36

**US3082221**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User entered 'bpm'	System	10 Sep 2020 13:23:36

US3082221

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 14:07:55
User entered '13'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:23:36

US3082221

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User entered 'breaths/min'	System	10 Sep 2020 13:23:36

US3082221

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 14:07:55
User entered '125'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:23:36



US3082221

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User entered 'mmHg'	System	10 Sep 2020 13:23:36

US3082221

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:04:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 14:07:55
User entered '81'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:23:36

US3082221

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User entered 'mmHg'	System	10 Sep 2020 13:23:36

**US3082221**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55

US3082221

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55

**US3082221**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:57:46**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:05:28
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:23:44

US3082221

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:05:28
User entered '10 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:23:44

US3082221

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:57:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:05:39
User closed query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	System	10 Sep 2020 13:25:00
User opened query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	System	10 Sep 2020 13:24:41
User entered '10 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:24:41



**US3082221**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:57:46**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:05:39
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:24:41

**US3082221**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:57:46**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:05:39
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:24:41

**US3082221**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:57:46**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:05:39
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:24:41

**US3082221**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:57:46**

*If Surgically sterile, date of surgery (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:05:39
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:24:41

**US3082221**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:57:46**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:05:39
User entered '0'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:24:41

US3082221

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:57:46

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:05:39
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:24:41

**US3082221**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:57:46**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:05:39
User entered '0'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:24:41

**US3082221**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:05:47
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:29



**US3082221**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:05:47
User entered '10 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:29

**US3082221**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:05:47
User entered 'Urine (URINE)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:29

**US3082221**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:05:47
User entered 'Negative (NEGATIVE)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:29

**US3082221**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:05:47
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:29

**US3082221**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:05:47
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:29

**US3082221**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:05:47
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:29

**US3082221**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User entered empty.	System	10 Sep 2020 13:25:29

US3082221

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:46

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:06:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:51



US3082221

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:46

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:06:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:51

US3082221

Folder: Screening

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**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:06:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:51

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Form: Risk of Exposure

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**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:06:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:51

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:06:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:51

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:06:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:51

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**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:06:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:51

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**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:06:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:51

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Folder: Screening

Form: Risk of Exposure

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:06:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:51



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Folder: Screening

Form: Risk of Exposure

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**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:06:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:51

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Form: Risk of Exposure

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**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:06:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:51

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:06:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:06:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:51

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**Folder: Screening**

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**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered 'I'	Erin Harrelson (b) (4)	10 Sep 2020 13:25:51

US3082221

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:46

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:06:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:46

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:06:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:51

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Folder: Screening

Form: Risk of Exposure

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[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:06:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:51



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Folder: Screening

Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:06:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:51

US3082221

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:46

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:06:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:51

US3082221

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered '0'	Erin Harrelson (b) (4)	10 Sep 2020 13:25:51

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:47:55
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:06:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:25:51

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:09
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:26:06

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:09
User entered '10 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:26:06

US3082221

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:57:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:09
User entered 'Clinic (Clinic)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:26:06

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'VISIT1'	System	10 Sep 2020 13:26:06



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:57:46

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:21
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Sep 2020 12:54:44

US3082221

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:57:46

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:21
User entered '112719'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Sep 2020 12:54:44

US3082221

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:57:46

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:21
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Sep 2020 12:54:44

US3082221

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:57:46

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 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:21
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:26:58

US3082221

Folder: Visit 1 Day 1

Form: Randomization

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Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:21
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:26:58

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:57:46**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:21
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:26:58

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:57:46**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:21
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:26:58

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**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:57:46**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:21
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:26:58



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Folder: Visit 1 Day 1

Form: Randomization

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[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:21
User entered 'No (N)'	Erin Harrelson (b) (4)	22 Sep 2020 19:46:42
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 05:55:10
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:55:09

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:57:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 14:08:22
User entered '65.5' in	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:57:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 14:08:22
User entered '176.5' lb	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:57:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 14:08:22
User entered '65.5' in	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:57:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 14:08:22
User entered '176.5' lb	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User accepted default value 'Pre-Dose (PREDOSE)'	Erin Harrelson (b) (4)	10 Sep 2020 13:57:57
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered '10 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57



**US3082221**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered '08:29'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered '10 Sep 2020 08:29'	System	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered '98.0' F	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered 'Other (Other)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered 'forehead'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered '66'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'bpm'	System	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered '13'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57



US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'breaths/min'	System	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered '125'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'mmHg'	System	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered '81'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'mmHg'	System	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:57:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 14:08:22
User entered '65.5' in	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:57:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Morgan Mathis (b) (4) (b) (4)	23 Oct 2020 14:08:22
User entered '176.5' lb	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User accepted default value 'Post-Dose (POSTDOSE)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57



US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered '10 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered '09:42'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered '10 Sep 2020 09:42'	System	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered '98.1' F	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered 'Other (Other)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered 'forehead'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered '68'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57



**US3082221**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'bpm'	System	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered '14'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'breaths/min'	System	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered '118'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'mmHg'	System	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:36
User entered '87'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'mmHg'	System	10 Sep 2020 13:57:57

US3082221

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:48
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:27:07



US3082221

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:48
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:27:07

US3082221

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:57:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:55
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:27:12

US3082221

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:57:46

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:55
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:27:12

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:55
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:27:12

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:55
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:27:12

US3082221

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:57:46

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:55
User closed query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:32:17
Query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". Please update as appropriate. ' answered with 'fsh sample not collected' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	26 Oct 2020 12:00:05
User entered 'No (N)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	26 Oct 2020 11:59:53
User opened query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 09:21:55
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:27:12

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:55
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:27:12

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:07:55
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:27:12



**US3082221**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered empty.	System	10 Sep 2020 13:27:12

US3082221

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:09:37
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:27:31

US3082221

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:09:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:27:31

US3082221

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

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 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:09:37
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:27:31

US3082221

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 13:27:31

US3082221

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:09:37
User entered '10 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:27:31

US3082221

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:09:37
User entered '09:10'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:27:31

US3082221

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered '10 Sep 2020 09:10'	System	10 Sep 2020 13:27:31



US3082221

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:09:37
User entered 'Left Arm (LEFT ARM)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:27:31

US3082221

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:09:37
User entered 'ONCE'	System	10 Sep 2020 13:27:31

US3082221

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 13:27:31

US3082221

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:57:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:09:58
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:31:15

US3082221

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:57:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:09:58
User entered '10 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:31:15

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:09:58
User entered '08:35'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:31:15

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered '10 Sep 2020 08:35'	System	10 Sep 2020 13:31:15

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 21:57:46**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:10:14
User entered '10 Sep 2020'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:31:37



**US3082221**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Erin Harrelson (b) (4)	10 Sep 2020 13:31:37

US3082221

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:57:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:10:14
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:31:37

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:10:14
User entered '08:39'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:31:37

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered '10 Sep 2020 08:39'	System	10 Sep 2020 13:31:37

US3082221

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:57:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Erin Harrelson (b) (4)	10 Sep 2020 13:31:37

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:10:14
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:31:37

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:57:46**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:10:14
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:31:37

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered empty.	System	10 Sep 2020 13:31:37



US3082221

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:57:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:10:27
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:31:43

**US3082221**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'I'	System	10 Sep 2020 13:31:43

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T09:46:29', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '11387261-933c-42ad-a821-fc7fe3d1372d' User entered 'Yes (Y)'	System	10 Sep 2020 13:46:53
	System	10 Sep 2020 13:46:53

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T09:46:34', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '11387261-933c-42ad-a821-fc7fe3d1372d' User entered '98.1'	System	10 Sep 2020 13:46:53
	System	10 Sep 2020 13:46:53

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T09:46:43', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '11387261-933c-42ad-a821-fc7fe3d1372d' User entered 'No (N)'	System	10 Sep 2020 13:46:53
	System	10 Sep 2020 13:46:53

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T09:46:48', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '11387261-933c-42ad-a821-fc7fe3d1372d' User entered '10 Sep 2020 09:46'	System	10 Sep 2020 13:46:53
	System	10 Sep 2020 13:46:53

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '10 Sep 2020 09:30'	System	10 Sep 2020 13:27:31



US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '10 Sep 2020 12:00'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T21:54:56', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'cf1bffa7-b367-41f3-9558-bee58ee84c20'	System	11 Sep 2020 01:55:16
User entered 'Yes (Y)'	System	11 Sep 2020 01:55:16

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T21:55:01', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'cf1bffa7-b367-41f3-9558-bee58ee84c20' User entered '98.2'	System	11 Sep 2020 01:55:16
	System	11 Sep 2020 01:55:16

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T21:55:05', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'cf1bffa7-b367-41f3-9558-bee58ee84c20'	System	11 Sep 2020 01:55:16
User entered 'No (N)'	System	11 Sep 2020 01:55:16

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T21:55:14', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'cf1bffa7-b367-41f3-9558-bee58ee84c20'	System	11 Sep 2020 01:55:16
User entered '10 Sep 2020 21:55'	System	11 Sep 2020 01:55:16

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '10 Sep 2020 12:55'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 13:27:31



US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 2'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-11T19:28:50', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1d84d61d-d4b1-4eec-9ded-b8db6850ae7a' User entered 'Yes (Y)'	System	11 Sep 2020 23:29:27
	System	11 Sep 2020 23:29:27

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-11T19:29:12', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1d84d61d-d4b1-4eec-9ded-b8db6850ae7a' User entered '97.9'	System	11 Sep 2020 23:29:27
	System	11 Sep 2020 23:29:27

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-11T19:29:15', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1d84d61d-d4b1-4eec-9ded-b8db6850ae7a' User entered 'No (N)'	System	11 Sep 2020 23:29:27
	System	11 Sep 2020 23:29:27

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-11T19:29:24', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1d84d61d-d4b1-4eec-9ded-b8db6850ae7a' User entered '11 Sep 2020 19:29'	System	11 Sep 2020 23:29:27
	System	11 Sep 2020 23:29:27

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 3'	System	10 Sep 2020 13:27:31



US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T10:34:21', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '6371fa3f-177f-4c12-94c0-b3ca0bf0a0d0' User entered 'Yes (Y)'	System	13 Sep 2020 14:34:36
	System	13 Sep 2020 14:34:36

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T10:34:25', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '6371fa3f-177f-4c12-94c0-b3ca0bf0a0d0' User entered '97.9'	System	13 Sep 2020 14:34:36
	System	13 Sep 2020 14:34:36

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T10:34:29', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '6371fa3f-177f-4c12-94c0-b3ca0bf0a0d0'	System	13 Sep 2020 14:34:36
User entered 'No (N)'	System	13 Sep 2020 14:34:36

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T10:34:33', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '6371fa3f-177f-4c12-94c0-b3ca0bf0a0d0' User entered '13 Sep 2020 10:34'	System	13 Sep 2020 14:34:36
	System	13 Sep 2020 14:34:36

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 4'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T23:59:30', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'dabe9a42-d1f5-4805-bd50-2efc2d542c15'	System	14 Sep 2020 03:59:48
User entered 'Yes (Y)'	System	14 Sep 2020 03:59:48



US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T23:59:38', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'dabe9a42-d1f5-4805-bd50-2efc2d542c15' User entered '98.0'	System	14 Sep 2020 03:59:48
	System	14 Sep 2020 03:59:48

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T23:59:41', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'dabe9a42-d1f5-4805-bd50-2efc2d542c15'	System	14 Sep 2020 03:59:48
User entered 'No (N)'	System	14 Sep 2020 03:59:48

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T23:59:45', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'dabe9a42-d1f5-4805-bd50-2efc2d542c15' User entered '13 Sep 2020 23:59'	System	14 Sep 2020 03:59:48
	System	14 Sep 2020 03:59:48

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 5'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T06:21:20', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '2319cb83-1a1f-48b4-b8b3-612c842bb720' User entered 'Yes (Y)'	System	15 Sep 2020 10:21:35
	System	15 Sep 2020 10:21:35

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T06:21:23', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '2319cb83-1a1f-48b4-b8b3-612c842bb720' User entered '98.2'	System	15 Sep 2020 10:21:35
	System	15 Sep 2020 10:21:35



US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T06:21:26', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '2319cb83-1a1f-48b4-b8b3-612c842bb720'	System	15 Sep 2020 10:21:35
User entered 'No (N)'	System	15 Sep 2020 10:21:35

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T06:21:30', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '2319cb83-1a1f-48b4-b8b3-612c842bb720' User entered '15 Sep 2020 06:21'	System	15 Sep 2020 10:21:35
	System	15 Sep 2020 10:21:35

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 6'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T20:09:33', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ec0fc6cf-7efd-4866-986b-2eb8e5c46508' User entered 'Yes (Y)'	System	16 Sep 2020 00:10:23
	System	16 Sep 2020 00:10:23

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T20:10:14', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ec0fc6cf-7efd-4866-986b-2eb8e5c46508' User entered '98.0'	System	16 Sep 2020 00:10:23
	System	16 Sep 2020 00:10:23

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T20:10:17', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ec0fc6cf-7efd-4866-986b-2eb8e5c46508'	System	16 Sep 2020 00:10:23
User entered 'No (N)'	System	16 Sep 2020 00:10:23



**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T20:10:19', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ec0fc6cf-7efd-4866-986b-2eb8e5c46508'	System	16 Sep 2020 00:10:23
User entered '15 Sep 2020 20:10'	System	16 Sep 2020 00:10:23

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 7'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-16T19:19:10', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'd5769f9c-37fd-40a0-8225-2f4265e18b95' User entered 'Yes (Y)'	System	16 Sep 2020 23:19:24
	System	16 Sep 2020 23:19:24

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-16T19:19:13', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'd5769f9c-37fd-40a0-8225-2f4265e18b95' User entered '97.9'	System	16 Sep 2020 23:19:24
	System	16 Sep 2020 23:19:24

US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-16T19:19:15', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'd5769f9c-37fd-40a0-8225-2f4265e18b95'	System	16 Sep 2020 23:19:24
User entered 'No (N)'	System	16 Sep 2020 23:19:24

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-16T19:19:20', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'd5769f9c-37fd-40a0-8225-2f4265e18b95'	System	16 Sep 2020 23:19:24
User entered '16 Sep 2020 19:19'	System	16 Sep 2020 23:19:24



US3082221

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T09:46:55', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ee426912-69fa-4618-a001-29eac640d8a7' User entered 'None (1)'	System	10 Sep 2020 13:47:45
	System	10 Sep 2020 13:47:45

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T09:46:57', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ee426912-69fa-4618-a001-29eac640d8a7' User entered 'No (N)'	System	10 Sep 2020 13:47:45
	System	10 Sep 2020 13:47:45

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T09:47:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ee426912-69fa-4618-a001-29eac640d8a7' User entered 'No (N)'	System	10 Sep 2020 13:47:45
	System	10 Sep 2020 13:47:45

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T09:47:04', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ee426912-69fa-4618-a001-29eac640d8a7'	System	10 Sep 2020 13:47:45
User entered 'None (1)'	System	10 Sep 2020 13:47:45

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T09:47:08', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ee426912-69fa-4618-a001-29eac640d8a7' User entered '10 Sep 2020 09:47'	System	10 Sep 2020 13:47:45
	System	10 Sep 2020 13:47:45



US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '10 Sep 2020 09:30'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '10 Sep 2020 12:00'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T21:55:20', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'c8eb1e31-f1fe-4d40-93d6-2173edefdec7' User entered 'None (1)'	System	11 Sep 2020 01:55:37
	System	11 Sep 2020 01:55:37

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T21:55:23', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'c8eb1e31-f1fe-4d40-93d6-2173edefdec'	System	11 Sep 2020 01:55:37
User entered 'No (N)'	System	11 Sep 2020 01:55:37

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T21:55:26', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'c8eb1e31-f1fe-4d40-93d6-2173edefdec7' User entered 'No (N)'	System	11 Sep 2020 01:55:37
	System	11 Sep 2020 01:55:37

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T21:55:33', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'c8eb1e31-f1fe-4d40-93d6-2173edefdec7' User entered 'None (1)'	System	11 Sep 2020 01:55:37
	System	11 Sep 2020 01:55:37

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T21:55:35', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'c8eb1e31-f1fe-4d40-93d6-2173edefdec7' User entered '10 Sep 2020 21:55'	System	11 Sep 2020 01:55:37
	System	11 Sep 2020 01:55:37



US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '10 Sep 2020 12:55'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 2'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-11T19:29:35', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '6d79b447-e8a2-490d-b130-9eedb828b07e' User entered 'None (1)'	System	11 Sep 2020 23:29:47
	System	11 Sep 2020 23:29:47

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-11T19:29:38', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '6d79b447-e8a2-490d-b130-9eedb828b07e' User entered 'No (N)'	System	11 Sep 2020 23:29:47
	System	11 Sep 2020 23:29:47

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-11T19:29:40', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '6d79b447-e8a2-490d-b130-9eedb828b07e' User entered 'No (N)'	System	11 Sep 2020 23:29:47
	System	11 Sep 2020 23:29:47

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-11T19:29:42', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '6d79b447-e8a2-490d-b130-9eedb828b07e' User entered 'None (1)'	System	11 Sep 2020 23:29:47
	System	11 Sep 2020 23:29:47

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-11T19:29:45', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '6d79b447-e8a2-490d-b130-9eedb828b07e' User entered '11 Sep 2020 19:29'	System	11 Sep 2020 23:29:47
	System	11 Sep 2020 23:29:47



US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 3'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T10:34:36', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'c4333540-dbdb-401b-b295-71b1eed934a9' User entered 'None (1)'	System	13 Sep 2020 14:34:49
	System	13 Sep 2020 14:34:49

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T10:34:39', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'c4333540-dbdb-401b-b295-71b1eed934a9' User entered 'No (N)'	System	13 Sep 2020 14:34:49
	System	13 Sep 2020 14:34:49

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T10:34:40', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'c4333540-dbdb-401b-b295-71b1eed934a9' User entered 'No (N)'	System	13 Sep 2020 14:34:49
	System	13 Sep 2020 14:34:49

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T10:34:42', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'c4333540-dbdb-401b-b295-71b1eed934a9' User entered 'None (1)'	System	13 Sep 2020 14:34:49
	System	13 Sep 2020 14:34:49

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T10:34:45', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'c4333540-dbdb-401b-b295-71b1eed934a9' User entered '13 Sep 2020 10:34'	System	13 Sep 2020 14:34:49
	System	13 Sep 2020 14:34:49



US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 4'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T23:59:49', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '60d55575-c03a-440e-b103-fbdc92a640c7'	System	14 Sep 2020 04:00:06
User entered 'None (1)'	System	14 Sep 2020 04:00:06

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T23:59:51', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '60d55575-c03a-440e-b103-fbdc92a640c7'	System	14 Sep 2020 04:00:06
User entered 'No (N)'	System	14 Sep 2020 04:00:06

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T23:59:53', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '60d55575-c03a-440e-b103-fbdc92a640c7' User entered 'No (N)'	System	14 Sep 2020 04:00:06
	System	14 Sep 2020 04:00:06

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T23:59:55', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '60d55575-c03a-440e-b103-fbdc92a640c7' User entered 'None (1)'	System	14 Sep 2020 04:00:06
	System	14 Sep 2020 04:00:06

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T23:59:58', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '60d55575-c03a-440e-b103-fbdc92a640c7' User entered '13 Sep 2020 23:59'	System	14 Sep 2020 04:00:06
	System	14 Sep 2020 04:00:06



US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 5'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T06:21:33', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '66bb923b-82aa-4d8b-af56-b4a92f3d2fe5'	System	15 Sep 2020 10:21:44
User entered 'None (1)'	System	15 Sep 2020 10:21:44

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T06:21:35', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '66bb923b-82aa-4d8b-af56-b4a92f3d2fe5'	System	15 Sep 2020 10:21:44
User entered 'No (N)'	System	15 Sep 2020 10:21:44

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T06:21:36', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '66bb923b-82aa-4d8b-af56-b4a92f3d2fe5' User entered 'No (N)'	System	15 Sep 2020 10:21:44
	System	15 Sep 2020 10:21:44

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T06:21:38', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '66bb923b-82aa-4d8b-af56-b4a92f3d2fe5'	System	15 Sep 2020 10:21:44
User entered 'None (1)'	System	15 Sep 2020 10:21:44

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T06:21:41', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '66bb923b-82aa-4d8b-af56-b4a92f3d2fe5' User entered '15 Sep 2020 06:21'	System	15 Sep 2020 10:21:44
	System	15 Sep 2020 10:21:44



US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 6'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T20:10:22', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'c5c350e9-e4ff-4166-925d-54e69755694a' User entered 'None (1)'	System	16 Sep 2020 00:10:32
	System	16 Sep 2020 00:10:32

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:46

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T20:10:24', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'c5c350e9-e4ff-4166-925d-54e69755694a' User entered 'No (N)'	System	16 Sep 2020 00:10:32
	System	16 Sep 2020 00:10:32

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T20:10:25', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'c5c350e9-e4ff-4166-925d-54e69755694a' User entered 'No (N)'	System	16 Sep 2020 00:10:32
	System	16 Sep 2020 00:10:32

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T20:10:26', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'c5c350e9-e4ff-4166-925d-54e69755694a' User entered 'None (1)'	System	16 Sep 2020 00:10:32
	System	16 Sep 2020 00:10:32

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T20:10:29', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'c5c350e9-e4ff-4166-925d-54e69755694a' User entered '15 Sep 2020 20:10'	System	16 Sep 2020 00:10:32
	System	16 Sep 2020 00:10:32



US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 7'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-16T19:19:23', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'f5a94c7d-65e7-4e13-b9db-05d3f216f117'	System	16 Sep 2020 23:19:35
User entered 'None (1)'	System	16 Sep 2020 23:19:35

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-16T19:19:25', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'f5a94c7d-65e7-4e13-b9db-05d3f216f117' User entered 'No (N)'	System	16 Sep 2020 23:19:35
	System	16 Sep 2020 23:19:35

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-16T19:19:26', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'f5a94c7d-65e7-4e13-b9db-05d3f216f117' User entered 'No (N)'	System	16 Sep 2020 23:19:35
	System	16 Sep 2020 23:19:35

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-16T19:19:27', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'f5a94c7d-65e7-4e13-b9db-05d3f216f117' User entered 'None (1)'	System	16 Sep 2020 23:19:35
	System	16 Sep 2020 23:19:35

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-16T19:19:30', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'f5a94c7d-65e7-4e13-b9db-05d3f216f117' User entered '16 Sep 2020 19:19'	System	16 Sep 2020 23:19:35
	System	16 Sep 2020 23:19:35



US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:57:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T09:47:14', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '5fb927c8-842b-434c-a350-e91d5c6d12fc' User entered 'None (0)'	System	10 Sep 2020 13:47:55
	System	10 Sep 2020 13:47:55

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:57:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T09:47:17', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '5fb927c8-842b-434c-a350-e91d5c6d12fc' User entered 'None (0)'	System	10 Sep 2020 13:47:55
	System	10 Sep 2020 13:47:55

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T09:47:22', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '5fb927c8-842b-434c-a350-e91d5c6d12fc' User entered 'None (0)'	System	10 Sep 2020 13:47:55
	System	10 Sep 2020 13:47:55

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T09:47:24', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '5fb927c8-842b-434c-a350-e91d5c6d12fc' User entered 'None (0)'	System	10 Sep 2020 13:47:55
	System	10 Sep 2020 13:47:55

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T09:47:26', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '5fb927c8-842b-434c-a350-e91d5c6d12fc' User entered 'None (0)'	System	10 Sep 2020 13:47:55
	System	10 Sep 2020 13:47:55



**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:57:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T09:47:28', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '5fb927c8-842b-434c-a350-e91d5c6d12fc' User entered 'None (0)'	System	10 Sep 2020 13:47:55
	System	10 Sep 2020 13:47:55

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T09:47:32', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '5fb927c8-842b-434c-a350-e91d5c6d12fc' User entered 'No (N)'	System	10 Sep 2020 13:47:55
	System	10 Sep 2020 13:47:55

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T09:47:35', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '5fb927c8-842b-434c-a350-e91d5c6d12fc' User entered '10 Sep 2020 09:47'	System	10 Sep 2020 13:47:55
	System	10 Sep 2020 13:47:55

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '10 Sep 2020 09:30'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '10 Sep 2020 12:00'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T21:55:39', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'f5fd220a-c549-4e32-ba40-ee7682f566b6' User entered 'None (0)'	System	11 Sep 2020 01:56:09
	System	11 Sep 2020 01:56:09

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T21:55:42', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'f5fd220a-c549-4e32-ba40-ee7682f566b6' User entered 'None (0)'	System	11 Sep 2020 01:56:09
	System	11 Sep 2020 01:56:09



US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T21:55:45', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'f5fd220a-c549-4e32-ba40-ee7682f566b6' User entered 'None (0)'	System	11 Sep 2020 01:56:09
	System	11 Sep 2020 01:56:09

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T21:55:48', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'f5fd220a-c549-4e32-ba40-ee7682f566b6' User entered 'None (0)'	System	11 Sep 2020 01:56:09
	System	11 Sep 2020 01:56:09

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T21:55:50', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'f5fd220a-c549-4e32-ba40-ee7682f566b6' User entered 'None (0)'	System	11 Sep 2020 01:56:09
	System	11 Sep 2020 01:56:09

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T21:55:52', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'f5fd220a-c549-4e32-ba40-ee7682f566b6' User entered 'None (0)'	System	11 Sep 2020 01:56:09
	System	11 Sep 2020 01:56:09

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T21:55:57', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'f5fd220a-c549-4e32-ba40-ee7682f566b6' User entered 'No (N)'	System	11 Sep 2020 01:56:09
	System	11 Sep 2020 01:56:09

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-10T21:56:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'f5fd220a-c549-4e32-ba40-ee7682f566b6'	System	11 Sep 2020 01:56:09
User entered '10 Sep 2020 21:56'	System	11 Sep 2020 01:56:09

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '10 Sep 2020 12:55'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 13:27:31



**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 2'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:57:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-11T19:29:48', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '60e1eda4-2595-49db-af21-5204674171cf' User entered 'None (0)'	System	11 Sep 2020 23:30:14
	System	11 Sep 2020 23:30:14

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:57:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-11T19:29:50', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '60e1eda4-2595-49db-af21-5204674171cf'	System	11 Sep 2020 23:30:14
User entered 'No interference with activity (1)'	System	11 Sep 2020 23:30:14

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-11T19:29:52', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '60e1eda4-2595-49db-af21-5204674171cf' User entered 'None (0)'	System	11 Sep 2020 23:30:14
	System	11 Sep 2020 23:30:14

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-11T19:29:56', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '60e1eda4-2595-49db-af21-5204674171cf' User entered 'None (0)'	System	11 Sep 2020 23:30:14
	System	11 Sep 2020 23:30:14

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:57:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-11T19:29:58', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '60e1eda4-2595-49db-af21-5204674171cf' User entered 'None (0)'	System	11 Sep 2020 23:30:14
	System	11 Sep 2020 23:30:14

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:57:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-11T19:29:59', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '60e1eda4-2595-49db-af21-5204674171cf' User entered 'None (0)'	System	11 Sep 2020 23:30:14
	System	11 Sep 2020 23:30:14

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-11T19:30:07', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '60e1eda4-2595-49db-af21-5204674171cf' User entered 'No (N)'	System	11 Sep 2020 23:30:14
	System	11 Sep 2020 23:30:14



**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-11T19:30:09', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '60e1eda4-2595-49db-af21-5204674171cf' User entered '11 Sep 2020 19:30'	System	11 Sep 2020 23:30:14
	System	11 Sep 2020 23:30:14

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 3'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:57:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T10:34:49', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '41841a20-5bab-4852-a582-56ecbc3167ae' User entered 'None (0)'	System	13 Sep 2020 14:35:12
	System	13 Sep 2020 14:35:12

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:57:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T10:34:50', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '41841a20-5bab-4852-a582-56ecbc3167ae' User entered 'None (0)'	System	13 Sep 2020 14:35:12
	System	13 Sep 2020 14:35:12

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T10:34:51', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '41841a20-5bab-4852-a582-56ecbc3167ae' User entered 'None (0)'	System	13 Sep 2020 14:35:12
	System	13 Sep 2020 14:35:12

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T10:34:53', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '41841a20-5bab-4852-a582-56ecbc3167ae' User entered 'None (0)'	System	13 Sep 2020 14:35:12
	System	13 Sep 2020 14:35:12



US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T10:34:54', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '41841a20-5bab-4852-a582-56ecbc3167ae' User entered 'None (0)'	System	13 Sep 2020 14:35:12
	System	13 Sep 2020 14:35:12

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:57:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T10:34:56', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '41841a20-5bab-4852-a582-56ecbc3167ae' User entered 'None (0)'	System	13 Sep 2020 14:35:12
	System	13 Sep 2020 14:35:12

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T10:35:01', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '41841a20-5bab-4852-a582-56ecbc3167ae' User entered 'No (N)'	System	13 Sep 2020 14:35:12
	System	13 Sep 2020 14:35:12

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-13T10:35:03', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '41841a20-5bab-4852-a582-56ecbc3167ae' User entered '13 Sep 2020 10:35'	System	13 Sep 2020 14:35:12
	System	13 Sep 2020 14:35:12

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 4'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:57:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-14T00:00:01', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '8be471e3-6db8-4638-947d-2d704e5a831f' User entered 'None (0)'	System	14 Sep 2020 04:00:17
	System	14 Sep 2020 04:00:17



US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-14T00:00:03', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '8be471e3-6db8-4638-947d-2d704e5a831f' User entered 'None (0)'	System	14 Sep 2020 04:00:17
	System	14 Sep 2020 04:00:17

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-14T00:00:04', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '8be471e3-6db8-4638-947d-2d704e5a831f' User entered 'None (0)'	System	14 Sep 2020 04:00:17
	System	14 Sep 2020 04:00:17

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-14T00:00:06', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '8be471e3-6db8-4638-947d-2d704e5a831f' User entered 'None (0)'	System	14 Sep 2020 04:00:17
	System	14 Sep 2020 04:00:17

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:57:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-14T00:00:07', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '8be471e3-6db8-4638-947d-2d704e5a831f' User entered 'None (0)'	System	14 Sep 2020 04:00:17
	System	14 Sep 2020 04:00:17

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:57:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-14T00:00:09', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '8be471e3-6db8-4638-947d-2d704e5a831f' User entered 'None (0)'	System	14 Sep 2020 04:00:17
	System	14 Sep 2020 04:00:17

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-14T00:00:11', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '8be471e3-6db8-4638-947d-2d704e5a831f' User entered 'No (N)'	System	14 Sep 2020 04:00:17
	System	14 Sep 2020 04:00:17

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-14T00:00:14', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '8be471e3-6db8-4638-947d-2d704e5a831f' User entered '14 Sep 2020 00:00'	System	14 Sep 2020 04:00:17
	System	14 Sep 2020 04:00:17

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 13:27:31



**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 5'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:57:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T06:21:44', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ac868c3b-0295-461c-b80a-193afca8cd3c' User entered 'None (0)'	System	15 Sep 2020 10:21:59
	System	15 Sep 2020 10:21:59

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:57:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T06:21:45', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ac868c3b-0295-461c-b80a-193afca8cd3c' User entered 'None (0)'	System	15 Sep 2020 10:21:59
	System	15 Sep 2020 10:21:59

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T06:21:47', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ac868c3b-0295-461c-b80a-193afca8cd3c' User entered 'None (0)'	System	15 Sep 2020 10:21:59
	System	15 Sep 2020 10:21:59

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T06:21:49', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ac868c3b-0295-461c-b80a-193afca8cd3c' User entered 'None (0)'	System	15 Sep 2020 10:21:59
	System	15 Sep 2020 10:21:59

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:57:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T06:21:50', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ac868c3b-0295-461c-b80a-193afca8cd3c' User entered 'None (0)'	System	15 Sep 2020 10:21:59
	System	15 Sep 2020 10:21:59

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:57:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T06:21:51', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ac868c3b-0295-461c-b80a-193afca8cd3c' User entered 'None (0)'	System	15 Sep 2020 10:21:59
	System	15 Sep 2020 10:21:59



US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T06:21:53', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ac868c3b-0295-461c-b80a-193afca8cd3c' User entered 'No (N)'	System	15 Sep 2020 10:21:59
	System	15 Sep 2020 10:21:59

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T06:21:56', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ac868c3b-0295-461c-b80a-193afca8cd3c' User entered '15 Sep 2020 06:21'	System	15 Sep 2020 10:21:59
	System	15 Sep 2020 10:21:59

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 6'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:57:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T20:10:32', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'fb253235-fb0c-46db-9fc2-8efb01c3b1aa' User entered 'None (0)'	System	16 Sep 2020 00:10:54
	System	16 Sep 2020 00:10:54

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T20:10:34', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'fb253235-fb0c-46db-9fc2-8efb01c3b1aa' User entered 'None (0)'	System	16 Sep 2020 00:10:54
	System	16 Sep 2020 00:10:54

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T20:10:35', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'fb253235-fb0c-46db-9fc2-8efb01c3b1aa' User entered 'None (0)'	System	16 Sep 2020 00:10:54
	System	16 Sep 2020 00:10:54



US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T20:10:36', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'fb253235-fb0c-46db-9fc2-8efb01c3b1aa' User entered 'None (0)'	System	16 Sep 2020 00:10:54
	System	16 Sep 2020 00:10:54

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:57:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T20:10:38', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'fb253235-fb0c-46db-9fc2-8efb01c3b1aa' User entered 'None (0)'	System	16 Sep 2020 00:10:54
	System	16 Sep 2020 00:10:54

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:57:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T20:10:39', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'fb253235-fb0c-46db-9fc2-8efb01c3b1aa' User entered 'None (0)'	System	16 Sep 2020 00:10:54
	System	16 Sep 2020 00:10:54

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T20:10:42', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'fb253235-fb0c-46db-9fc2-8efb01c3b1aa' User entered 'No (N)'	System	16 Sep 2020 00:10:54
	System	16 Sep 2020 00:10:54

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-15T20:10:44', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'fb253235-fb0c-46db-9fc2-8efb01c3b1aa' User entered '15 Sep 2020 20:10'	System	16 Sep 2020 00:10:54
	System	16 Sep 2020 00:10:54

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 13:27:31

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 7'	System	10 Sep 2020 13:27:31



**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:57:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-16T19:19:32', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1d226e65-cbe6-4f28-ae58-60f0b27d259d' User entered 'None (0)'	System	16 Sep 2020 23:19:50
	System	16 Sep 2020 23:19:50

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:57:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-16T19:19:34', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1d226e65-cbe6-4f28-ae58-60f0b27d259d' User entered 'None (0)'	System	16 Sep 2020 23:19:50
	System	16 Sep 2020 23:19:50

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-16T19:19:35', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1d226e65-cbe6-4f28-ae58-60f0b27d259d' User entered 'None (0)'	System	16 Sep 2020 23:19:50
	System	16 Sep 2020 23:19:50

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-16T19:19:36', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1d226e65-cbe6-4f28-ae58-60f0b27d259d' User entered 'None (0)'	System	16 Sep 2020 23:19:50
	System	16 Sep 2020 23:19:50

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:57:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-16T19:19:37', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1d226e65-cbe6-4f28-ae58-60f0b27d259d' User entered 'None (0)'	System	16 Sep 2020 23:19:50
	System	16 Sep 2020 23:19:50

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:57:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-16T19:19:39', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1d226e65-cbe6-4f28-ae58-60f0b27d259d' User entered 'None (0)'	System	16 Sep 2020 23:19:50
	System	16 Sep 2020 23:19:50

US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-16T19:19:42', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1d226e65-cbe6-4f28-ae58-60f0b27d259d' User entered 'No (N)'	System	16 Sep 2020 23:19:50
	System	16 Sep 2020 23:19:50

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-09-16T19:19:44', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1d226e65-cbe6-4f28-ae58-60f0b27d259d' User entered '16 Sep 2020 19:19'	System	16 Sep 2020 23:19:50
	System	16 Sep 2020 23:19:50



US3082221

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:11:05
User entered 'Yes (Y)'	Ayssa Valente (b) (4) (b) (4)	17 Sep 2020 15:56:44

**US3082221**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:11:05
User entered '17 Sep 2020'	Ayssa Valente (b) (4) (b) (4)	17 Sep 2020 15:56:44

US3082221

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:57:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:11:05
User entered 'Contact Made (CONTACT MADE)'	Ayssa Valente (b) (4) (b) (4)	17 Sep 2020 15:56:44

**US3082221**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:11:05
User entered empty.	Ayssa Valente (b) (4) (b) (4)	17 Sep 2020 15:56:44

US3082221

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:57:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:11:29
User entered 'Yes (Y)'	Ayssa Valente (b) (4) (b) (4)	17 Sep 2020 15:56:48

**US3082221**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'I'	System	17 Sep 2020 15:56:48



**US3082221**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:11:46
User entered 'Yes (Y)'	Angie Northcott (b) (4) (b) (4)	24 Sep 2020 17:26:57

**US3082221**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:11:46
User entered '24 Sep 2020'	Angie Northcott (b) (4) (b) (4)	24 Sep 2020 17:26:57

**US3082221**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:11:46
User entered 'Contact Made (CONTACT MADE)'	Angie Northcott (b) (4) (b) (4)	24 Sep 2020 17:26:57

US3082221

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:57:46

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:11:46
User entered empty.	Angie Northcott (b) (4) (b) (4)	24 Sep 2020 17:26:57

US3082221

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:57:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:21:29
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered 'Yes (Y)'	(b) (4) Angie Northcott (b) (4) (b) (4)	24 Sep 2020 17:27:03

**US3082221**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'I'	System	24 Sep 2020 17:27:03

**US3082221**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:12:04
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	01 Oct 2020 14:13:54

**US3082221**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:12:04
User entered '01 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	01 Oct 2020 14:13:54



**US3082221**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:12:04
User entered 'Contact Made (CONTACT MADE)'	Erin Harrelson (b) (4) (b) (4)	01 Oct 2020 14:13:54

US3082221

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:57:46

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:12:04
User entered empty.	Erin Harrelson (b) (4) (b) (4)	01 Oct 2020 14:13:54

**US3082221**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:12:26
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	01 Oct 2020 14:13:57

**US3082221**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'I'	System	01 Oct 2020 14:13:57

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:45
User entered 'Yes (Y)'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:13:25

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:45
User entered '13 Oct 2020'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:13:25

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:45
User entered 'Clinic (Clinic)'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:13:25

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'VISIT2'	System	13 Oct 2020 15:13:25



US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User accepted default value 'Pre-Dose (PREDOSE)'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:03
User entered 'Yes (Y)'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:03
User entered '13 Oct 2020'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:03
User entered '11:03'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered '13 Oct 2020 11:03'	System	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:03
User entered '97.5' F	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:03
User entered 'Other (Other)'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:03
User entered 'forehead'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20



**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:03
User entered '60'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'bpm'	System	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:03
User entered '16'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'breaths/min'	System	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:03
User entered '119'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'mmHg'	System	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:03
User entered '72'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'mmHg'	System	13 Oct 2020 15:25:20



US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User accepted default value 'Post-Dose (POSTDOSE)'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:03
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 16:24:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 16:24:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	13 Oct 2020 16:24:40
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 15:25:20
User entered empty.	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:03
User entered '13 Oct 2020'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:03
User entered '12:18' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	13 Oct 2020 16:24:40
User entered empty.	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered '13 Oct 2020 12:18'	System	13 Oct 2020 16:24:40
User entered empty.	System	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:03
User entered '97.8' F reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	13 Oct 2020 16:24:40
User entered empty.	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:03
User entered 'Other (Other)' reason for change: Data Entry Error	Erin Harrelson (b) (4)	13 Oct 2020 16:24:40
User entered empty.	(b) (4) Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:03
User entered 'forehead' reason for change: Data Entry Error	Erin Harrelson (b) (4)	13 Oct 2020 16:24:40
User entered empty.	(b) (4) Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20



US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:03
User entered '65' reason for change: Data Entry Error	Erin Harrelson (b) (4)	13 Oct 2020 16:24:40
User entered empty.	(b) (4) Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'bpm'	System	13 Oct 2020 16:24:40
User entered empty.	System	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:03
User entered '16' reason for change: Data Entry Error	Erin Harrelson (b) (4)	13 Oct 2020 16:24:40
User entered empty.	(b) (4) Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'breaths/min'	System	13 Oct 2020 16:24:40
User entered empty.	System	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:03
User entered '107' reason for change: Data Entry Error	Erin Harrelson (b) (4)	13 Oct 2020 16:24:40
User entered empty.	(b) (4) Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'mmHg'	System	13 Oct 2020 16:24:40
User entered empty.	System	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:03
User entered '74' reason for change: Data Entry Error	Erin Harrelson (b) (4)	13 Oct 2020 16:24:40
User entered empty.	(b) (4) Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:25:20

US3082221

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'mmHg'	System	13 Oct 2020 16:24:40
User entered empty.	System	13 Oct 2020 15:25:20



US3082221

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:15
User entered 'Yes (Y)'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:34:47

US3082221

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:15
User entered '13 Oct 2020'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:34:47

US3082221

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:57:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:23
User entered 'Yes (Y)'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:21:36

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:23
User entered '13 Oct 2020'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:21:36

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:23
User entered 'Urine (URINE)'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:21:36

US3082221

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:57:46

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:23
User entered 'Negative (NEGATIVE)'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:21:36

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:23
User entered 'No (N)'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:21:36

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:23
User entered empty.	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:21:36



**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:23
User entered empty.	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:21:36

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered empty.	System	13 Oct 2020 15:21:36

US3082221

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:54
User entered 'Yes (Y)'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:52:32

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:57:46**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:54
User entered empty.	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:52:32

US3082221

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

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 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:54
User entered empty.	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:52:32

US3082221

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 15:52:32

US3082221

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:54
User entered '13 Oct 2020'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:52:32

US3082221

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:54
User entered '11:48'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:52:32



US3082221

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered '13 Oct 2020 11:48'	System	13 Oct 2020 15:52:32

US3082221

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:17:54
User entered 'Left Arm (LEFT ARM)'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:52:32

US3082221

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 14:17:54
User entered 'ONCE'	System	13 Oct 2020 15:52:32

US3082221

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 15:52:32

US3082221

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:57:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:20:42
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered 'Yes (Y)'	(b) (4) Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:23:56

US3082221

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:57:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:20:42
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered '13 Oct 2020'	(b) (4) Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:23:56

US3082221

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:57:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:20:42
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered '11:20'	(b) (4) Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:23:56

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered '13 Oct 2020 11:20'	System	13 Oct 2020 15:23:56



US3082221

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:57:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:18:32
User entered '13 Oct 2020'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:24:07

US3082221

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:57:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:24:07

US3082221

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:57:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:18:32
User entered 'Yes (Y)'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:24:07

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:18:32
User entered '11:22'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:24:07

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered '13 Oct 2020 11:22'	System	13 Oct 2020 15:24:07

US3082221

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:57:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:24:07

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:18:32
User entered 'No (N)'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:24:07

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:57:46**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:18:32
User entered empty.	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:24:07



**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered empty.	System	13 Oct 2020 15:24:07

US3082221

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:57:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:18:40
User entered 'Yes (Y)'	Brandy Lowman (b) (4) (b) (4)	13 Oct 2020 15:24:11

**US3082221**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'I'	System	13 Oct 2020 15:24:11

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T12:18:23', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1e21938f-44ed-4ce5-9c97-7f585f177d70'	System	13 Oct 2020 16:18:40
User entered 'Yes (Y)'	System	13 Oct 2020 16:18:40

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T12:18:27', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1e21938f-44ed-4ce5-9c97-7f585f177d70'	System	13 Oct 2020 16:18:40
User entered '97.8'	System	13 Oct 2020 16:18:40

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T12:18:32', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1e21938f-44ed-4ce5-9c97-7f585f177d70'	System	13 Oct 2020 16:18:40
User entered 'No (N)'	System	13 Oct 2020 16:18:40

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T12:18:38', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1e21938f-44ed-4ce5-9c97-7f585f177d70'	System	13 Oct 2020 16:18:40
User entered '13 Oct 2020 12:18'	System	13 Oct 2020 16:18:40



US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '13 Oct 2020 12:08'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '13 Oct 2020 14:38'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T20:54:39', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '06285a31-ff58-4a3c-93c7-1da417d974dc' User entered 'Yes (Y)'	System	14 Oct 2020 00:55:18
	System	14 Oct 2020 00:55:18

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T20:54:42', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '06285a31-ff58-4a3c-93c7-1da417d974dc' User entered '97.1'	System	14 Oct 2020 00:55:18
	System	14 Oct 2020 00:55:18

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T20:54:59', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '06285a31-ff58-4a3c-93c7-1da417d974dc' User entered 'No (N)'	System	14 Oct 2020 00:55:18
	System	14 Oct 2020 00:55:18

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T20:55:15', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '06285a31-ff58-4a3c-93c7-1da417d974dc' User entered '13 Oct 2020 20:55'	System	14 Oct 2020 00:55:18
	System	14 Oct 2020 00:55:18

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '13 Oct 2020 15:33'	System	13 Oct 2020 15:52:32



US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 2'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T05:17:59', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '2937585a-01e1-4f7a-8b9f-6bc56c5ad820' User entered 'Yes (Y)'	System	15 Oct 2020 09:18:09
	System	15 Oct 2020 09:18:09

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T05:18:02', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '2937585a-01e1-4f7a-8b9f-6bc56c5ad820' User entered '97.2'	System	15 Oct 2020 09:18:09
	System	15 Oct 2020 09:18:09

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T05:18:04', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '2937585a-01e1-4f7a-8b9f-6bc56c5ad820' User entered 'No (N)'	System	15 Oct 2020 09:18:09
	System	15 Oct 2020 09:18:09

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T05:18:07', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '2937585a-01e1-4f7a-8b9f-6bc56c5ad820' User entered '15 Oct 2020 05:18'	System	15 Oct 2020 09:18:09
	System	15 Oct 2020 09:18:09

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 15:52:32



US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 3'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T22:03:25', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '4a695c1a-e568-4171-9b21-8866558cfa5b' User entered 'Yes (Y)'	System	16 Oct 2020 02:03:40
	System	16 Oct 2020 02:03:40

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T22:03:30', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '4a695c1a-e568-4171-9b21-8866558cfa5b' User entered '97.3'	System	16 Oct 2020 02:03:40
	System	16 Oct 2020 02:03:40

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T22:03:32', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '4a695c1a-e568-4171-9b21-8866558cfa5b' User entered 'No (N)'	System	16 Oct 2020 02:03:40
	System	16 Oct 2020 02:03:40

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T22:03:36', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '4a695c1a-e568-4171-9b21-8866558cfa5b' User entered '15 Oct 2020 22:03'	System	16 Oct 2020 02:03:40
	System	16 Oct 2020 02:03:40

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 4'	System	13 Oct 2020 15:52:32



US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T09:21:22', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ef5ed2da-6fae-4b4d-bf8b-52329caf27cb' User entered 'Yes (Y)'	System	17 Oct 2020 13:21:35
	System	17 Oct 2020 13:21:35

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T09:21:27', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ef5ed2da-6fae-4b4d-bf8b-52329caf27cb' User entered '97.1'	System	17 Oct 2020 13:21:35
	System	17 Oct 2020 13:21:35

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T09:21:29', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ef5ed2da-6fae-4b4d-bf8b-52329caf27cb'	System	17 Oct 2020 13:21:35
User entered 'No (N)'	System	17 Oct 2020 13:21:35

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T09:21:32', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ef5ed2da-6fae-4b4d-bf8b-52329caf27cb' User entered '17 Oct 2020 09:21'	System	17 Oct 2020 13:21:35
	System	17 Oct 2020 13:21:35

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 5'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T22:09:43', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '3becb8ec-2685-4514-9fda-9f1b7d5766ff' User entered 'Yes (Y)'	System	18 Oct 2020 02:11:07
	System	18 Oct 2020 02:11:07



US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T22:10:04', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '3becb8ec-2685-4514-9fda-9f1b7d5766ff' User entered '97.4'	System	18 Oct 2020 02:11:07
	System	18 Oct 2020 02:11:07

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T22:11:02', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '3becb8ec-2685-4514-9fda-9f1b7d5766ff'	System	18 Oct 2020 02:11:07
User entered 'No (N)'	System	18 Oct 2020 02:11:07

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T22:11:05', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '3becb8ec-2685-4514-9fda-9f1b7d5766ff' User entered '17 Oct 2020 22:11'	System	18 Oct 2020 02:11:07
	System	18 Oct 2020 02:11:07

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 6'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-18T22:08:19', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ecf92d8f-3b0b-4bad-ab71-702249f305e1' User entered 'Yes (Y)'	System	19 Oct 2020 02:08:30
	System	19 Oct 2020 02:08:30

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-18T22:08:23', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ecf92d8f-3b0b-4bad-ab71-702249f305e1' User entered '97.6'	System	19 Oct 2020 02:08:30
	System	19 Oct 2020 02:08:30



US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-18T22:08:26', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ecf92d8f-3b0b-4bad-ab71-702249f305e1'	System	19 Oct 2020 02:08:30
User entered 'No (N)'	System	19 Oct 2020 02:08:30

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-18T22:08:28', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ecf92d8f-3b0b-4bad-ab71-702249f305e1' User entered '18 Oct 2020 22:08'	System	19 Oct 2020 02:08:30
	System	19 Oct 2020 02:08:30

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 7'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-19T21:18:49', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '8553f42a-3d41-492a-89e8-430c627b83d9' User entered 'Yes (Y)'	System	20 Oct 2020 01:19:00
	System	20 Oct 2020 01:19:00

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-19T21:18:55', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '8553f42a-3d41-492a-89e8-430c627b83d9' User entered '97.3'	System	20 Oct 2020 01:19:00
	System	20 Oct 2020 01:19:00

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:46

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-19T21:18:57', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '8553f42a-3d41-492a-89e8-430c627b83d9' User entered 'No (N)'	System	20 Oct 2020 01:19:00
	System	20 Oct 2020 01:19:00



**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-19T21:18:59', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '8553f42a-3d41-492a-89e8-430c627b83d9' User entered '19 Oct 2020 21:18'	System	20 Oct 2020 01:19:00
	System	20 Oct 2020 01:19:00

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T12:18:44', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '63dcf8ab-628c-4360-bf53-bce973874d65'	System	13 Oct 2020 16:18:57
User entered 'None (1)'	System	13 Oct 2020 16:18:57

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T12:18:46', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '63dcf8ab-628c-4360-bf53-bce973874d65' User entered 'No (N)'	System	13 Oct 2020 16:18:57
	System	13 Oct 2020 16:18:57

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T12:18:49', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '63dcf8ab-628c-4360-bf53-bce973874d65' User entered 'No (N)'	System	13 Oct 2020 16:18:57
	System	13 Oct 2020 16:18:57

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T12:18:51', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '63dcf8ab-628c-4360-bf53-bce973874d65'	System	13 Oct 2020 16:18:57
User entered 'None (1)'	System	13 Oct 2020 16:18:57



**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T12:18:54', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '63dcf8ab-628c-4360-bf53-bce973874d65' User entered '13 Oct 2020 12:18'	System	13 Oct 2020 16:18:57
	System	13 Oct 2020 16:18:57

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '13 Oct 2020 12:08'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '13 Oct 2020 14:38'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T20:55:18', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '04c46501-f31f-46a2-9f84-4672142999f5'	System	14 Oct 2020 00:55:28
User entered 'None (1)'	System	14 Oct 2020 00:55:28

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T20:55:20', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '04c46501-f31f-46a2-9f84-4672142999f5'	System	14 Oct 2020 00:55:28
User entered 'No (N)'	System	14 Oct 2020 00:55:28

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T20:55:22', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '04c46501-f31f-46a2-9f84-4672142999f5'	System	14 Oct 2020 00:55:28
User entered 'No (N)'	System	14 Oct 2020 00:55:28

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T20:55:23', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '04c46501-f31f-46a2-9f84-4672142999f5'	System	14 Oct 2020 00:55:28
User entered 'None (1)'	System	14 Oct 2020 00:55:28



**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T20:55:27', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '04c46501-f31f-46a2-9f84-4672142999f5' User entered '13 Oct 2020 20:55'	System	14 Oct 2020 00:55:28
	System	14 Oct 2020 00:55:28

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '13 Oct 2020 15:33'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 2'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T05:18:11', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '6ec7a55d-ba01-4a39-8a32-652eab8c78db' User entered 'None (1)'	System	15 Oct 2020 09:18:22
	System	15 Oct 2020 09:18:22

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T05:18:13', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '6ec7a55d-ba01-4a39-8a32-652eab8c78db' User entered 'No (N)'	System	15 Oct 2020 09:18:22
	System	15 Oct 2020 09:18:22

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T05:18:14', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '6ec7a55d-ba01-4a39-8a32-652eab8c78db' User entered 'No (N)'	System	15 Oct 2020 09:18:22
	System	15 Oct 2020 09:18:22

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T05:18:16', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '6ec7a55d-ba01-4a39-8a32-652eab8c78db' User entered 'None (1)'	System	15 Oct 2020 09:18:22
	System	15 Oct 2020 09:18:22



**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T05:18:19', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '6ec7a55d-ba01-4a39-8a32-652eab8c78db' User entered '15 Oct 2020 05:18'	System	15 Oct 2020 09:18:22
	System	15 Oct 2020 09:18:22

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 3'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T22:03:39', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '033fdb24-1e45-404b-be3c-71ce85969a14'	System	16 Oct 2020 02:03:50
User entered 'None (1)'	System	16 Oct 2020 02:03:50

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T22:03:41', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '033fdb24-1e45-404b-be3c-71ce85969a14' User entered 'No (N)'	System	16 Oct 2020 02:03:50
	System	16 Oct 2020 02:03:50

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T22:03:42', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '033fdb24-1e45-404b-be3c-71ce85969a14' User entered 'No (N)'	System	16 Oct 2020 02:03:50
	System	16 Oct 2020 02:03:50

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T22:03:44', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '033fdb24-1e45-404b-be3c-71ce85969a14' User entered 'None (1)'	System	16 Oct 2020 02:03:50
	System	16 Oct 2020 02:03:50



**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T22:03:46', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '033fdb24-1e45-404b-be3c-71ce85969a14' User entered '15 Oct 2020 22:03'	System	16 Oct 2020 02:03:50
	System	16 Oct 2020 02:03:50

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 4'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T09:21:35', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '883bb28e-e754-42a4-835a-b1396d0bc8b9' User entered 'None (1)'	System	17 Oct 2020 13:21:44
	System	17 Oct 2020 13:21:44

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T09:21:37', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '883bb28e-e754-42a4-835a-b1396d0bc8b9' User entered 'No (N)'	System	17 Oct 2020 13:21:44
	System	17 Oct 2020 13:21:44

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T09:21:39', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '883bb28e-e754-42a4-835a-b1396d0bc8b9' User entered 'No (N)'	System	17 Oct 2020 13:21:44
	System	17 Oct 2020 13:21:44

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T09:21:40', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '883bb28e-e754-42a4-835a-b1396d0bc8b9' User entered 'None (1)'	System	17 Oct 2020 13:21:44
	System	17 Oct 2020 13:21:44



**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T09:21:42', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '883bb28e-e754-42a4-835a-b1396d0bc8b9' User entered '17 Oct 2020 09:21'	System	17 Oct 2020 13:21:44
	System	17 Oct 2020 13:21:44

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 5'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T22:11:08', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '4842ac15-3720-4110-bf10-562298c15e5c' User entered 'None (1)'	System	18 Oct 2020 02:11:18
	System	18 Oct 2020 02:11:18

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T22:11:09', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '4842ac15-3720-4110-bf10-562298c15e5c' User entered 'No (N)'	System	18 Oct 2020 02:11:18
	System	18 Oct 2020 02:11:18

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T22:11:11', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '4842ac15-3720-4110-bf10-562298c15e5c' User entered 'No (N)'	System	18 Oct 2020 02:11:18
	System	18 Oct 2020 02:11:18

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T22:11:13', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '4842ac15-3720-4110-bf10-562298c15e5c' User entered 'None (1)'	System	18 Oct 2020 02:11:18
	System	18 Oct 2020 02:11:18



**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T22:11:15', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '4842ac15-3720-4110-bf10-562298c15e5c' User entered '17 Oct 2020 22:11'	System	18 Oct 2020 02:11:18
	System	18 Oct 2020 02:11:18

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 6'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-18T22:07:38', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'a266d684-acbd-432e-84b9-fef28f7225f1'	System	19 Oct 2020 02:07:56
User entered 'None (1)'	System	19 Oct 2020 02:07:56

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-18T22:07:44', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'a266d684-acbd-432e-84b9-fef28f7225f1' User entered 'No (N)'	System	19 Oct 2020 02:07:56
	System	19 Oct 2020 02:07:56

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-18T22:07:51', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'a266d684-acbd-432e-84b9-fef28f7225f1' User entered 'No (N)'	System	19 Oct 2020 02:07:56
	System	19 Oct 2020 02:07:56

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-18T22:07:52', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'a266d684-acbd-432e-84b9-fef28f7225f1' User entered 'None (1)'	System	19 Oct 2020 02:07:56
	System	19 Oct 2020 02:07:56



**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-18T22:07:54', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'a266d684-acbd-432e-84b9-fef28f7225f1' User entered '18 Oct 2020 22:07'	System	19 Oct 2020 02:07:56
	System	19 Oct 2020 02:07:56

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 7'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-19T21:19:02', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'da5272d7-e308-4e69-8b6a-65ae8fa992dd'	System	20 Oct 2020 01:19:11
User entered 'None (1)'	System	20 Oct 2020 01:19:11

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-19T21:19:03', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'da5272d7-e308-4e69-8b6a-65ae8fa992dd' User entered 'No (N)'	System	20 Oct 2020 01:19:11
	System	20 Oct 2020 01:19:11

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-19T21:19:05', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'da5272d7-e308-4e69-8b6a-65ae8fa992dd' User entered 'No (N)'	System	20 Oct 2020 01:19:11
	System	20 Oct 2020 01:19:11

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-19T21:19:06', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'da5272d7-e308-4e69-8b6a-65ae8fa992dd'	System	20 Oct 2020 01:19:11
User entered 'None (1)'	System	20 Oct 2020 01:19:11



**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-19T21:19:09', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'da5272d7-e308-4e69-8b6a-65ae8fa992dd' User entered '19 Oct 2020 21:19'	System	20 Oct 2020 01:19:11
	System	20 Oct 2020 01:19:11

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T12:19:03', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'd012b807-3e92-4bde-96e8-9f71aa87e1c3' User entered 'None (0)'	System	13 Oct 2020 16:19:20
	System	13 Oct 2020 16:19:20

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:57:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T12:19:05', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'd012b807-3e92-4bde-96e8-9f71aa87e1c3' User entered 'None (0)'	System	13 Oct 2020 16:19:20
	System	13 Oct 2020 16:19:20

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T12:19:06', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'd012b807-3e92-4bde-96e8-9f71aa87e1c3' User entered 'None (0)'	System	13 Oct 2020 16:19:20
	System	13 Oct 2020 16:19:20

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T12:19:08', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'd012b807-3e92-4bde-96e8-9f71aa87e1c3' User entered 'None (0)'	System	13 Oct 2020 16:19:20
	System	13 Oct 2020 16:19:20



US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T12:19:09', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'd012b807-3e92-4bde-96e8-9f71aa87e1c3' User entered 'None (0)'	System	13 Oct 2020 16:19:20
	System	13 Oct 2020 16:19:20

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:57:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T12:19:11', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'd012b807-3e92-4bde-96e8-9f71aa87e1c3' User entered 'None (0)'	System	13 Oct 2020 16:19:20
	System	13 Oct 2020 16:19:20

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T12:19:14', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'd012b807-3e92-4bde-96e8-9f71aa87e1c3'	System	13 Oct 2020 16:19:20
User entered 'No (N)'	System	13 Oct 2020 16:19:20

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T12:19:18', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'd012b807-3e92-4bde-96e8-9f71aa87e1c3' User entered '13 Oct 2020 12:19'	System	13 Oct 2020 16:19:20
	System	13 Oct 2020 16:19:20

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '13 Oct 2020 12:08'	System	13 Oct 2020 15:52:32

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '13 Oct 2020 14:38'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 15:52:32

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T20:55:29', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '91efbb34-723d-4eb2-b433-9db51b002966' User entered 'None (0)'	System	14 Oct 2020 00:55:43
	System	14 Oct 2020 00:55:43



**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T20:55:31', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '91efbb34-723d-4eb2-b433-9db51b002966' User entered 'None (0)'	System	14 Oct 2020 00:55:43
	System	14 Oct 2020 00:55:43

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T20:55:32', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '91efbb34-723d-4eb2-b433-9db51b002966' User entered 'None (0)'	System	14 Oct 2020 00:55:43
	System	14 Oct 2020 00:55:43

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T20:55:34', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '91efbb34-723d-4eb2-b433-9db51b002966' User entered 'None (0)'	System	14 Oct 2020 00:55:43
	System	14 Oct 2020 00:55:43

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T20:55:35', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '91efbb34-723d-4eb2-b433-9db51b002966' User entered 'None (0)'	System	14 Oct 2020 00:55:43
	System	14 Oct 2020 00:55:43

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T20:55:37', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '91efbb34-723d-4eb2-b433-9db51b002966' User entered 'None (0)'	System	14 Oct 2020 00:55:43
	System	14 Oct 2020 00:55:43

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T20:55:39', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '91efbb34-723d-4eb2-b433-9db51b002966' User entered 'No (N)'	System	14 Oct 2020 00:55:43
	System	14 Oct 2020 00:55:43

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-13T20:55:41', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '91efbb34-723d-4eb2-b433-9db51b002966'	System	14 Oct 2020 00:55:43
User entered '13 Oct 2020 20:55'	System	14 Oct 2020 00:55:43

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '13 Oct 2020 15:33'	System	13 Oct 2020 15:52:32



US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 2'	System	13 Oct 2020 15:52:32

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:57:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T05:18:22', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '3880cea9-1135-4341-9aec-808e61102e05' User entered 'None (0)'	System	15 Oct 2020 09:18:38
	System	15 Oct 2020 09:18:38

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:57:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T05:18:23', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '3880cea9-1135-4341-9aec-808e61102e05' User entered 'None (0)'	System	15 Oct 2020 09:18:38
	System	15 Oct 2020 09:18:38

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T05:18:25', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '3880cea9-1135-4341-9aec-808e61102e05' User entered 'None (0)'	System	15 Oct 2020 09:18:38
	System	15 Oct 2020 09:18:38

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T05:18:27', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '3880cea9-1135-4341-9aec-808e61102e05' User entered 'None (0)'	System	15 Oct 2020 09:18:38
	System	15 Oct 2020 09:18:38

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T05:18:28', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '3880cea9-1135-4341-9aec-808e61102e05' User entered 'None (0)'	System	15 Oct 2020 09:18:38
	System	15 Oct 2020 09:18:38

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:57:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T05:18:30', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '3880cea9-1135-4341-9aec-808e61102e05' User entered 'None (0)'	System	15 Oct 2020 09:18:38
	System	15 Oct 2020 09:18:38



US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T05:18:35', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '3880cea9-1135-4341-9aec-808e61102e05' User entered 'No (N)'	System	15 Oct 2020 09:18:38
	System	15 Oct 2020 09:18:38

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T05:18:37', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '3880cea9-1135-4341-9aec-808e61102e05' User entered '15 Oct 2020 05:18'	System	15 Oct 2020 09:18:38
	System	15 Oct 2020 09:18:38

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 15:52:32

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 3'	System	13 Oct 2020 15:52:32

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:57:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T22:03:49', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '02fc632c-8d5e-47bf-b8d1-e6118767164e' User entered 'None (0)'	System	16 Oct 2020 02:04:11
	System	16 Oct 2020 02:04:11

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:57:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T22:03:50', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '02fc632c-8d5e-47bf-b8d1-e6118767164e' User entered 'None (0)'	System	16 Oct 2020 02:04:11
	System	16 Oct 2020 02:04:11

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T22:03:52', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '02fc632c-8d5e-47bf-b8d1-e6118767164e' User entered 'None (0)'	System	16 Oct 2020 02:04:11
	System	16 Oct 2020 02:04:11



US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T22:03:53', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '02fc632c-8d5e-47bf-b8d1-e6118767164e' User entered 'None (0)'	System	16 Oct 2020 02:04:11
	System	16 Oct 2020 02:04:11

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:57:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T22:03:55', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '02fc632c-8d5e-47bf-b8d1-e6118767164e' User entered 'None (0)'	System	16 Oct 2020 02:04:11
	System	16 Oct 2020 02:04:11

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:57:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T22:03:56', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '02fc632c-8d5e-47bf-b8d1-e6118767164e' User entered 'None (0)'	System	16 Oct 2020 02:04:11
	System	16 Oct 2020 02:04:11

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T22:04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '02fc632c-8d5e-47bf-b8d1-e6118767164e' User entered 'No (N)'	System	16 Oct 2020 02:04:11
	System	16 Oct 2020 02:04:11

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-15T22:04:03', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '02fc632c-8d5e-47bf-b8d1-e6118767164e' User entered '15 Oct 2020 22:04'	System	16 Oct 2020 02:04:11
	System	16 Oct 2020 02:04:11

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 15:52:32

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 4'	System	13 Oct 2020 15:52:32



**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:57:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T09:21:47', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'b58ce863-3d41-43cf-b354-082c768c52bb' User entered 'None (0)'	System	17 Oct 2020 13:22:02
	System	17 Oct 2020 13:22:02

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:57:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T09:21:49', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'b58ce863-3d41-43cf-b354-082c768c52bb' User entered 'None (0)'	System	17 Oct 2020 13:22:02
	System	17 Oct 2020 13:22:02

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T09:21:50', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'b58ce863-3d41-43cf-b354-082c768c52bb' User entered 'None (0)'	System	17 Oct 2020 13:22:02
	System	17 Oct 2020 13:22:02

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T09:21:52', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'b58ce863-3d41-43cf-b354-082c768c52bb' User entered 'None (0)'	System	17 Oct 2020 13:22:02
	System	17 Oct 2020 13:22:02

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T09:21:54', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'b58ce863-3d41-43cf-b354-082c768c52bb' User entered 'None (0)'	System	17 Oct 2020 13:22:02
	System	17 Oct 2020 13:22:02

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:57:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T09:21:55', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'b58ce863-3d41-43cf-b354-082c768c52bb' User entered 'None (0)'	System	17 Oct 2020 13:22:02
	System	17 Oct 2020 13:22:02

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T09:21:58', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'b58ce863-3d41-43cf-b354-082c768c52bb' User entered 'No (N)'	System	17 Oct 2020 13:22:02
	System	17 Oct 2020 13:22:02

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T09:21:59', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'b58ce863-3d41-43cf-b354-082c768c52bb' User entered '17 Oct 2020 09:21'	System	17 Oct 2020 13:22:02
	System	17 Oct 2020 13:22:02



**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 15:52:32

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 5'	System	13 Oct 2020 15:52:32

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:57:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T22:11:23', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '108fde19-ebab-4100-afd3-afb6b37e8066' User entered 'None (0)'	System	18 Oct 2020 02:11:38
	System	18 Oct 2020 02:11:38

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:57:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T22:11:26', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '108fde19-ebab-4100-afd3-afb6b37e8066' User entered 'None (0)'	System	18 Oct 2020 02:11:38
	System	18 Oct 2020 02:11:38

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T22:11:27', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '108fde19-ebab-4100-afd3-afb6b37e8066' User entered 'None (0)'	System	18 Oct 2020 02:11:38
	System	18 Oct 2020 02:11:38

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T22:11:29', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '108fde19-ebab-4100-afd3-afb6b37e8066' User entered 'None (0)'	System	18 Oct 2020 02:11:38
	System	18 Oct 2020 02:11:38

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:57:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T22:11:30', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '108fde19-ebab-4100-afd3-afb6b37e8066' User entered 'None (0)'	System	18 Oct 2020 02:11:38
	System	18 Oct 2020 02:11:38



**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:57:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T22:11:32', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '108fde19-ebab-4100-afd3-afb6b37e8066' User entered 'None (0)'	System	18 Oct 2020 02:11:38
	System	18 Oct 2020 02:11:38

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T22:11:34', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '108fde19-ebab-4100-afd3-afb6b37e8066' User entered 'No (N)'	System	18 Oct 2020 02:11:38
	System	18 Oct 2020 02:11:38

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-17T22:11:36', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '108fde19-ebab-4100-afd3-afb6b37e8066' User entered '17 Oct 2020 22:11'	System	18 Oct 2020 02:11:38
	System	18 Oct 2020 02:11:38

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 15:52:32

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 6'	System	13 Oct 2020 15:52:32

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:57:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-18T22:07:57', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'a765968d-c8a7-4491-8810-150312a3b135' User entered 'None (0)'	System	19 Oct 2020 02:08:19
	System	19 Oct 2020 02:08:19

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:57:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-18T22:07:59', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'a765968d-c8a7-4491-8810-150312a3b135' User entered 'None (0)'	System	19 Oct 2020 02:08:19
	System	19 Oct 2020 02:08:19



US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-18T22:08:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'a765968d-c8a7-4491-8810-150312a3b135' User entered 'None (0)'	System	19 Oct 2020 02:08:19
	System	19 Oct 2020 02:08:19

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-18T22:08:04', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'a765968d-c8a7-4491-8810-150312a3b135' User entered 'None (0)'	System	19 Oct 2020 02:08:19
	System	19 Oct 2020 02:08:19

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:57:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-18T22:08:06', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'a765968d-c8a7-4491-8810-150312a3b135' User entered 'None (0)'	System	19 Oct 2020 02:08:19
	System	19 Oct 2020 02:08:19

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:57:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-18T22:08:08', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'a765968d-c8a7-4491-8810-150312a3b135' User entered 'None (0)'	System	19 Oct 2020 02:08:19
	System	19 Oct 2020 02:08:19

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-18T22:08:09', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'a765968d-c8a7-4491-8810-150312a3b135'	System	19 Oct 2020 02:08:19
User entered 'No (N)'	System	19 Oct 2020 02:08:19

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-18T22:08:14', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'a765968d-c8a7-4491-8810-150312a3b135' User entered '18 Oct 2020 22:08'	System	19 Oct 2020 02:08:19
	System	19 Oct 2020 02:08:19

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 15:52:32

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 15:52:32



US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	13 Oct 2020 15:52:32
User entered 'Day 7'	System	13 Oct 2020 15:52:32

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:57:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-19T21:19:11', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1fbbde41-fc4b-479f-ba3e-65801a2654ff' User entered 'None (0)'	System	20 Oct 2020 01:19:29
	System	20 Oct 2020 01:19:29

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:57:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-19T21:19:13', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1fbbde41-fc4b-479f-ba3e-65801a2654ff' User entered 'None (0)'	System	20 Oct 2020 01:19:29
	System	20 Oct 2020 01:19:29

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-19T21:19:17', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1fbbde41-fc4b-479f-ba3e-65801a2654ff' User entered 'None (0)'	System	20 Oct 2020 01:19:29
	System	20 Oct 2020 01:19:29

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-19T21:19:19', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1fbbde41-fc4b-479f-ba3e-65801a2654ff' User entered 'None (0)'	System	20 Oct 2020 01:19:29
	System	20 Oct 2020 01:19:29

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:57:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-19T21:19:20', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1fbbde41-fc4b-479f-ba3e-65801a2654ff' User entered 'None (0)'	System	20 Oct 2020 01:19:29
	System	20 Oct 2020 01:19:29

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:57:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-19T21:19:22', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1fbbde41-fc4b-479f-ba3e-65801a2654ff' User entered 'None (0)'	System	20 Oct 2020 01:19:29
	System	20 Oct 2020 01:19:29

US3082221

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-19T21:19:24', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1fbbde41-fc4b-479f-ba3e-65801a2654ff' User entered 'No (N)'	System	20 Oct 2020 01:19:29
	System	20 Oct 2020 01:19:29



**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-10-19T21:19:27', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '1fbbde41-fc4b-479f-ba3e-65801a2654ff' User entered '19 Oct 2020 21:19'	System	20 Oct 2020 01:19:29
	System	20 Oct 2020 01:19:29

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 15:52:32

**US3082221**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:57:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 15:52:32

**US3082221**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:19:03
User entered 'Yes (Y)'	Angie Northcott (b) (4) (b) (4)	20 Oct 2020 15:08:45

**US3082221**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:19:03
User entered '20 Oct 2020'	Angie Northcott (b) (4) (b) (4)	20 Oct 2020 15:08:45

**US3082221**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:19:03
User entered 'Contact Made (CONTACT MADE)'	Angie Northcott (b) (4) (b) (4)	20 Oct 2020 15:08:45

US3082221

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:57:46

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:19:03
User entered empty.	Angie Northcott (b) (4) (b) (4)	20 Oct 2020 15:08:45

**US3082221**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:19:14
User entered 'Yes (Y)'	Angie Northcott (b) (4) (b) (4)	20 Oct 2020 15:08:49



**US3082221**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'I'	System	20 Oct 2020 15:08:49

**US3082221**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:19:44
User entered 'Yes (Y)'	Angie Northcott (b) (4) (b) (4)	27 Oct 2020 16:18:25

**US3082221**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:19:44
User entered '27 Oct 2020'	Angie Northcott (b) (4) (b) (4)	27 Oct 2020 16:18:25

**US3082221**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:19:44
User entered 'Contact Made (CONTACT MADE)'	Angie Northcott (b) (4) (b) (4)	27 Oct 2020 16:18:25

US3082221

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:57:46

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:19:44
User entered empty.	Angie Northcott (b) (4) (b) (4)	27 Oct 2020 16:18:25

**US3082221**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:19:52
User entered 'Yes (Y)'	Angie Northcott (b) (4) (b) (4)	27 Oct 2020 16:18:30

**US3082221**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'I'	System	27 Oct 2020 16:18:30

**US3082221**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:20:02
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	03 Nov 2020 14:45:18



**US3082221**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:20:02
User entered '03 Nov 2020'	Erin Harrelson (b) (4) (b) (4)	03 Nov 2020 14:45:18

US3082221

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:57:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:20:02
User entered 'Contact Made (CONTACT MADE)'	Erin Harrelson (b) (4) (b) (4)	03 Nov 2020 14:45:18

**US3082221**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:20:02
User entered empty.	Erin Harrelson (b) (4) (b) (4)	03 Nov 2020 14:45:18

**US3082221**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:20:11
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	03 Nov 2020 14:45:34

**US3082221**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'I'	System	03 Nov 2020 14:45:34

**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:20:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:49:54

**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:20:34
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 16:49:54

**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:20:34
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Nov 2020 16:49:54



**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'VISIT3'	System	11 Nov 2020 16:49:54

**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:20:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:50:53

**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:20:45
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 16:50:53

**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:20:45
User entered '11:06'	(b) (4), (b) (6)	11 Nov 2020 16:50:53

**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered '11 Nov 2020 11:06'	System	11 Nov 2020 16:50:53

US3082221

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:20:45
User entered '98.6' F	(b) (4), (b) (6)	11 Nov 2020 16:50:53

**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:20:45
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Nov 2020 16:50:53

**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:20:45
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:50:53



**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:20:45
User entered '86'	(b) (4), (b) (6)	11 Nov 2020 16:50:53

**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'bpm'	System	11 Nov 2020 16:50:53

**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:20:45
User entered '15'	(b) (4), (b) (6)	11 Nov 2020 16:50:53

US3082221

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'breaths/min'	System	11 Nov 2020 16:50:53

US3082221

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:20:45
User entered '122'	(b) (4), (b) (6)	11 Nov 2020 16:50:53

**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'mmHg'	System	11 Nov 2020 16:50:53

**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:20:45
User entered '83'	(b) (4), (b) (6)	11 Nov 2020 16:50:53

US3082221

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'mmHg'	System	11 Nov 2020 16:50:53



US3082221

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48

**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48

US3082221

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:21:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:51:20

**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:57:46**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:21:16
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 16:51:20

**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:21:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:51:42

**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:21:38
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 16:51:42

**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:21:38
User entered '11:27'	(b) (4), (b) (6)	11 Nov 2020 16:51:42

**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered '11 Nov 2020 11:27'	System	11 Nov 2020 16:51:42



**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:21:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:51:48

**US3082221**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'I'	System	11 Nov 2020 16:51:48

US3082221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 64'	System	10 Sep 2020 13:27:31

US3082221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

[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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-11-11T11:29:50', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'd908d77d-2153-42bc-828d-406ee1df18b0' User entered 'No (N)'	System	11 Nov 2020 16:30:03
	System	11 Nov 2020 16:30:03

US3082221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-11-11T11:29:54', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'd908d77d-2153-42bc-828d-406ee1df18b0'	System	11 Nov 2020 16:30:03
User entered 'No (N)'	System	11 Nov 2020 16:30:03

**US3082221**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-11-11T11:29:58', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'd908d77d-2153-42bc-828d-406ee1df18b0' User entered '11 Nov 2020 11:29:58'	System	11 Nov 2020 16:30:03
	System	11 Nov 2020 16:30:03

**US3082221**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered '10 Nov 2020 00:01'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered '14 Nov 2020 23:59'	System	10 Sep 2020 13:27:31



**US3082221**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered 'Day 71'	System	10 Sep 2020 13:27:31

US3082221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

[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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-11-19T11:38:15', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '3071c083-61dd-442d-b170-e85433fa4a52'	System	19 Nov 2020 16:38:24
User entered 'No (N)'	System	19 Nov 2020 16:38:24

US3082221

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

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 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-11-19T11:38:17', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '3071c083-61dd-442d-b170-e85433fa4a52'	System	19 Nov 2020 16:38:24
User entered 'No (N)'	System	19 Nov 2020 16:38:24

**US3082221**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-11-19T11:38:21', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '3071c083-61dd-442d-b170-e85433fa4a52' User entered '19 Nov 2020 11:38:21'	System	19 Nov 2020 16:38:24
	System	19 Nov 2020 16:38:24

**US3082221**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered '17 Nov 2020 00:01'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:58:33
Data entry locked.	System	10 Sep 2020 13:27:31
User entered '21 Nov 2020 23:59'	System	10 Sep 2020 13:27:31

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-11-24T06:26:56', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '968e6452-bc94-4f2b-b2a2-dd1a0be05793'	System	24 Nov 2020 11:27:06
User entered 'No (N)'	System	24 Nov 2020 11:27:06



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-11-24T06:26:57', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '968e6452-bc94-4f2b-b2a2-dd1a0be05793'	System	24 Nov 2020 11:27:06
User entered 'No (N)'	System	24 Nov 2020 11:27:06

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-11-24T06:27:01', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '968e6452-bc94-4f2b-b2a2-dd1a0be05793' User entered '24 Nov 2020 06:27:01'	System	24 Nov 2020 11:27:06
	System	24 Nov 2020 11:27:06

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-11-28T10:02:11', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'c3a5b10a-c940-46a1-b71c-c8f38f38fed3' User entered 'No (N)'	System	28 Nov 2020 15:02:21

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-11-28T10:02:15', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'c3a5b10a-c940-46a1-b71c-c8f38f38fed3' User entered 'No (N)'	System	28 Nov 2020 15:02:21

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-11-28T10:02:18', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'c3a5b10a-c940-46a1-b71c-c8f38f38fed3' User entered '28 Nov 2020 10:02:18'	System	28 Nov 2020 15:02:21
	System	28 Nov 2020 15:02:21



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-12-07T12:04:56', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'f5668f17-f68e-43df-8bbc-fb4af946fbfa' User entered 'No (N)'	System	07 Dec 2020 17:05:05

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-12-07T12:04:57', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'f5668f17-f68e-43df-8bbc-fb4af946fbfa' User entered 'No (N)'	System	07 Dec 2020 17:05:05

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-12-07T12:05:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'f5668f17-f68e-43df-8bbc-fb4af946fbfa' User entered '07 Dec 2020 12:05:00'	System	07 Dec 2020 17:05:05
	System	07 Dec 2020 17:05:05

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-12-12T06:24:01', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '9a536993-d762-4bf3-91a5-7a5e00dcc438'	System	12 Dec 2020 11:24:09
User entered 'No (N)'	System	12 Dec 2020 11:24:09

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-12-12T06:24:02', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '9a536993-d762-4bf3-91a5-7a5e00dcc438'	System	12 Dec 2020 11:24:09
User entered 'No (N)'	System	12 Dec 2020 11:24:09

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-12-12T06:24:05', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '9a536993-d762-4bf3-91a5-7a5e00dcc438' User entered '12 Dec 2020 06:24:05'	System	12 Dec 2020 11:24:09
	System	12 Dec 2020 11:24:09

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-12-19T09:12:55', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '521a2ecb-e037-4c7c-82e3-747265f8e374'	System	19 Dec 2020 14:13:09
User entered 'No (N)'	System	19 Dec 2020 14:13:09



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-12-19T09:13:03', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '521a2ecb-e037-4c7c-82e3-747265f8e374'	System	19 Dec 2020 14:13:09
User entered 'No (N)'	System	19 Dec 2020 14:13:09

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-12-19T09:13:06', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '521a2ecb-e037-4c7c-82e3-747265f8e374' User entered '19 Dec 2020 09:13:06'	System	19 Dec 2020 14:13:09
	System	19 Dec 2020 14:13:09

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-12-29T17:59:32', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '917ef1b0-fa29-4ac2-a118-cbbb68fc4228'	System	29 Dec 2020 22:59:41
User entered 'No (N)'	System	29 Dec 2020 22:59:41

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-12-29T17:59:35', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '917ef1b0-fa29-4ac2-a118-cbbb68fc4228'	System	29 Dec 2020 22:59:41
User entered 'No (N)'	System	29 Dec 2020 22:59:41

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2020-12-29T17:59:38', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '917ef1b0-fa29-4ac2-a118-cbbb68fc4228' User entered '29 Dec 2020 17:59:38'	System	29 Dec 2020 22:59:41
	System	29 Dec 2020 22:59:41



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-01-02T05:46:13', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'fe343c11-7c2e-4500-ac6a-6961bd682ed3' User entered 'No (N)'	System	02 Jan 2021 10:46:22

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-01-02T05:46:16', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'fe343c11-7c2e-4500-ac6a-6961bd682ed3'	System	02 Jan 2021 10:46:22
User entered 'No (N)'	System	02 Jan 2021 10:46:22

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-01-02T05:46:19', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'fe343c11-7c2e-4500-ac6a-6961bd682ed3' User entered '02 Jan 2021 05:46:19'	System	02 Jan 2021 10:46:22
	System	02 Jan 2021 10:46:22

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-01-10T21:39:05', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '4fa7a168-e046-4cf9-b1a9-8d25d51722bf' User entered 'No (N)'	System	11 Jan 2021 02:39:16
	System	11 Jan 2021 02:39:16

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-01-10T21:39:08', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '4fa7a168-e046-4cf9-b1a9-8d25d51722bf'	System	11 Jan 2021 02:39:16
User entered 'No (N)'	System	11 Jan 2021 02:39:16

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-01-10T21:39:12', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '4fa7a168-e046-4cf9-b1a9-8d25d51722bf' User entered '10 Jan 2021 21:39:12'	System	11 Jan 2021 02:39:16
	System	11 Jan 2021 02:39:16

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-01-16T14:39:52', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '58fbdf6a-a0e7-4d6c-b8af-7627e5045141'	System	16 Jan 2021 19:40:11
User entered 'No (N)'	System	16 Jan 2021 19:40:11



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-01-16T14:40:03', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '58fbdf6a-a0e7-4d6c-b8af-7627e5045141'	System	16 Jan 2021 19:40:11
User entered 'No (N)'	System	16 Jan 2021 19:40:11

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-01-16T14:40:06', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '58fbdf6a-a0e7-4d6c-b8af-7627e5045141' User entered '16 Jan 2021 14:40:06'	System	16 Jan 2021 19:40:11
	System	16 Jan 2021 19:40:11

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-01-25T12:33:38', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '37ae3e28-ef4b-4d3f-a91f-cf411aaa30e1' User entered 'No (N)'	System	25 Jan 2021 17:33:49
	System	25 Jan 2021 17:33:49

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-01-25T12:33:40', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '37ae3e28-ef4b-4d3f-a91f-cf411aaa30e1'	System	25 Jan 2021 17:33:49
User entered 'No (N)'	System	25 Jan 2021 17:33:49

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-01-25T12:33:46', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '37ae3e28-ef4b-4d3f-a91f-cf411aaa30e1' User entered '25 Jan 2021 12:33:46'	System	25 Jan 2021 17:33:49



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-02-02T21:08:30', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '0f2090f4-4a6c-4e73-a540-2899bd53ec68' User entered 'No (N)'	System	03 Feb 2021 02:13:04

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-02-02T21:08:39', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '0f2090f4-4a6c-4e73-a540-2899bd53ec68'	System	03 Feb 2021 02:13:04
User entered 'No (N)'	System	03 Feb 2021 02:13:04

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-02-02T21:08:42', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '0f2090f4-4a6c-4e73-a540-2899bd53ec68' User entered '02 Feb 2021 21:08:42'	System	03 Feb 2021 02:13:04
	System	03 Feb 2021 02:13:04

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-02-07T22:41:29', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '61f02230-fe70-4046-b369-2530ecb79675'	System	08 Feb 2021 03:41:35
User entered 'No (N)'	System	08 Feb 2021 03:41:35

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-02-07T22:41:30', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '61f02230-fe70-4046-b369-2530ecb79675'	System	08 Feb 2021 03:41:35
User entered 'No (N)'	System	08 Feb 2021 03:41:35

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-02-07T22:41:33', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '61f02230-fe70-4046-b369-2530ecb79675' User entered '07 Feb 2021 22:41:33'	System	08 Feb 2021 03:41:35
	System	08 Feb 2021 03:41:35

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-02-17T12:55:43', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '9d83fed6-8074-49f0-9e45-db316efa97b8' User entered 'No (N)'	System	17 Feb 2021 17:56:25
	System	17 Feb 2021 17:56:25



US3082221

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:46

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-02-17T12:55:47', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '9d83fed6-8074-49f0-9e45-db316efa97b8' User entered 'No (N)'	System	17 Feb 2021 17:56:25
	System	17 Feb 2021 17:56:25

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-02-17T12:55:51', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '9d83fed6-8074-49f0-9e45-db316efa97b8' User entered '17 Feb 2021 12:55:51'	System	17 Feb 2021 17:56:25
	System	17 Feb 2021 17:56:25

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-02-21T14:11:14', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ce02e45f-cc13-4ee2-bc0d-d287c12a1b01'	System	21 Feb 2021 19:11:22
User entered 'No (N)'	System	21 Feb 2021 19:11:22

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-02-21T14:11:16', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ce02e45f-cc13-4ee2-bc0d-d287c12a1b01'	System	21 Feb 2021 19:11:22
User entered 'No (N)'	System	21 Feb 2021 19:11:22

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-02-21T14:11:19', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'ce02e45f-cc13-4ee2-bc0d-d287c12a1b01'	System	21 Feb 2021 19:11:22
User entered '21 Feb 2021 14:11:19'	System	21 Feb 2021 19:11:22



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-03-01T15:29:27-05:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '30bd0c6e-75eb-4741-879a-31b915dd5ec0'	System	01 Mar 2021 20:29:37
User entered 'No (N)'	System	01 Mar 2021 20:29:37

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-03-01T15:29:29-05:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '30bd0c6e-75eb-4741-879a-31b915dd5ec0'	System	01 Mar 2021 20:29:37
User entered 'No (N)'	System	01 Mar 2021 20:29:37

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-03-01T15:29:32-05:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '30bd0c6e-75eb-4741-879a-31b915dd5ec0'	System	01 Mar 2021 20:29:37
User entered '01 Mar 2021 15:29:32'	System	01 Mar 2021 20:29:37

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-03-08T22:31:51-05:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'b53bfd15-6971-4b01-8743-67e24fcfecc7'	System	09 Mar 2021 03:32:04
User entered 'No (N)'	System	09 Mar 2021 03:32:04

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-03-08T22:31:53-05:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'b53bfd15-6971-4b01-8743-67e24fcfecc7'	System	09 Mar 2021 03:32:04
User entered 'No (N)'	System	09 Mar 2021 03:32:04

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-03-08T22:31:56-05:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'b53bfd15-6971-4b01-8743-67e24fcfecc7'	System	09 Mar 2021 03:32:04
User entered '08 Mar 2021 22:31:56'	System	09 Mar 2021 03:32:04

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-03-15T12:46:29-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '3d46a910-5c8a-46fe-96fc-37e3cc284544'	System	15 Mar 2021 16:46:39
User entered 'No (N)'	System	15 Mar 2021 16:46:39



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-03-15T12:46:30-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '3d46a910-5c8a-46fe-96fc-37e3cc284544'	System	15 Mar 2021 16:46:39
User entered 'No (N)'	System	15 Mar 2021 16:46:39

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-03-15T12:46:33-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '3d46a910-5c8a-46fe-96fc-37e3cc284544'	System	15 Mar 2021 16:46:39
User entered '15 Mar 2021 12:46:33'	System	15 Mar 2021 16:46:39

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-03-20T06:31:43-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '69890ccb-b0cc-4d5d-93d7-c4c9bc87f6ad'	System	20 Mar 2021 10:31:49
User entered 'No (N)'	System	20 Mar 2021 10:31:49

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-03-20T06:31:45-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '69890ccb-b0cc-4d5d-93d7-c4c9bc87f6ad'	System	20 Mar 2021 10:31:49
User entered 'No (N)'	System	20 Mar 2021 10:31:49

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-03-20T06:31:48-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '69890ccb-b0cc-4d5d-93d7-c4c9bc87f6ad' User entered '20 Mar 2021 06:31:48'	System	20 Mar 2021 10:31:49
	System	20 Mar 2021 10:31:49



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-03-28T06:28:42-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'b266fdc3-365b-4b90-bbf3-b27429a2c1a7'	System	28 Mar 2021 10:28:51
User entered 'No (N)'	System	28 Mar 2021 10:28:51

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-03-28T06:28:43-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'b266fdc3-365b-4b90-bbf3-b27429a2c1a7'	System	28 Mar 2021 10:28:51
User entered 'No (N)'	System	28 Mar 2021 10:28:51

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-03-28T06:28:47-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'b266fdc3-365b-4b90-bbf3-b27429a2c1a7'	System	28 Mar 2021 10:28:51
User entered '28 Mar 2021 06:28:47'	System	28 Mar 2021 10:28:51

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-04-07T10:12:52-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '21582fc7-4f50-407d-8531-2c21bf6b9ed0' User entered 'No (N)'	System	07 Apr 2021 14:13:02
	System	07 Apr 2021 14:13:02

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-04-07T10:12:53-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '21582fc7-4f50-407d-8531-2c21bf6b9ed0'	System	07 Apr 2021 14:13:02
User entered 'No (N)'	System	07 Apr 2021 14:13:02

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-04-07T10:12:56-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '21582fc7-4f50-407d-8531-2c21bf6b9ed0'	System	07 Apr 2021 14:13:02
User entered '07 Apr 2021 10:12:56'	System	07 Apr 2021 14:13:02

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-04-13T18:06:05-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '84a34f37-4baa-4516-a3c4-27238ffd61ed'	System	13 Apr 2021 22:08:07
User entered 'No (N)'	System	13 Apr 2021 22:08:07



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-04-13T18:06:07-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '84a34f37-4baa-4516-a3c4-27238ffd61ed'	System	13 Apr 2021 22:08:07
User entered 'No (N)'	System	13 Apr 2021 22:08:07

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-04-13T18:06:09-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '84a34f37-4baa-4516-a3c4-27238ffd61ed'	System	13 Apr 2021 22:08:07
User entered '13 Apr 2021 18:06:09'	System	13 Apr 2021 22:08:07

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-04-17T06:33:09-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '945d7518-d72d-4ecb-809b-d71b314303a7'	System	17 Apr 2021 10:33:26
User entered 'No (N)'	System	17 Apr 2021 10:33:26

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-04-17T06:33:19-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '945d7518-d72d-4ecb-809b-d71b314303a7'	System	17 Apr 2021 10:33:26
User entered 'No (N)'	System	17 Apr 2021 10:33:26

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-04-17T06:33:25-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '945d7518-d72d-4ecb-809b-d71b314303a7'	System	17 Apr 2021 10:33:26
User entered '17 Apr 2021 06:33:25'	System	17 Apr 2021 10:33:26



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-04-26T12:01:35-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'f6824f92-4df1-4e7e-a53e-b59eff3adec5' User entered 'No (N)'	System	26 Apr 2021 16:05:26

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-04-26T12:01:37-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'f6824f92-4df1-4e7e-a53e-b59eff3adec5'	System	26 Apr 2021 16:05:26
User entered 'No (N)'	System	26 Apr 2021 16:05:26

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-04-26T12:01:39-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'f6824f92-4df1-4e7e-a53e-b59eff3adec5'	System	26 Apr 2021 16:05:26
User entered '26 Apr 2021 12:01:39'	System	26 Apr 2021 16:05:26

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-05-03T12:51:08-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'fa422d76-3bc2-4956-aad4-75fcea6d602e'	System	03 May 2021 16:51:21
User entered 'No (N)'	System	03 May 2021 16:51:21

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-05-03T12:51:10-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'fa422d76-3bc2-4956-aad4-75fcea6d602e'	System	03 May 2021 16:51:21
User entered 'No (N)'	System	03 May 2021 16:51:21

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-05-03T12:51:13-04:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: 'fa422d76-3bc2-4956-aad4-75fceaafd602e'	System	03 May 2021 16:51:21
User entered '03 May 2021 12:51:13'	System	03 May 2021 16:51:21

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 06:56:36



**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 06:56:36

**US3082221**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:56:36
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 06:56:36

US3082221

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 21:57:46**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 00:32:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-03-01T15:29:38-05:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '62782fdf-a564-499a-9b2e-73bb92f72ed2'	System	01 Mar 2021 20:29:43
User entered 'No (N)'	System	01 Mar 2021 20:29:43

**US3082221**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 00:32:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BB89A6E-95DF-4264-947D-862C53F46C2C)', Time: '2021-03-01T15:29:41-05:00', User OID: 'PatientReportedOutcome (US3082221)', ODM File OID: '62782fdf-a564-499a-9b2e-73bb92f72ed2'	System	01 Mar 2021 20:29:43
User entered '01 Mar 2021 15:29:41'	System	01 Mar 2021 20:29:43



**US3082221**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:22:11
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	08 Dec 2020 15:41:02

**US3082221**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:22:11
User entered '08 Dec 2020'	Erin Harrelson (b) (4) (b) (4)	08 Dec 2020 15:41:02

**US3082221**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:22:11
User entered 'Contact Made (CONTACT MADE)'	Erin Harrelson (b) (4) (b) (4)	08 Dec 2020 15:41:02

**US3082221**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:22:11
User entered empty.	Erin Harrelson (b) (4) (b) (4)	08 Dec 2020 15:41:02

US3082221

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:57:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:22:24
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	08 Dec 2020 15:41:07

**US3082221**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:26:48
User entered 'I'	System	08 Dec 2020 15:41:07

**US3082221**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:51:28
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:22:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 14:22:12

**US3082221**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:51:28
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:22:34
User entered '11 Jan 2021'	(b) (4), (b) (6)	11 Feb 2021 14:22:12



**US3082221**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:51:28
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:22:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Feb 2021 14:22:12

**US3082221**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:51:28
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:22:34
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 14:22:12

**US3082221**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:51:28
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:22:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 14:22:16

**US3082221**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:51:28
User entered 'I'	System	11 Feb 2021 14:22:16

**US3082221**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:51:28
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 14:22:25

**US3082221**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:51:28
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:07
User entered '11 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 14:22:25

**US3082221**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:51:28
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Feb 2021 14:22:25

US3082221

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:57:46

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:51:28
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:07
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 14:22:25



**US3082221**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:51:28
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:23:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 14:22:30

**US3082221**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:51:28
User entered '1'	System	11 Feb 2021 14:22:30

**US3082221**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:50
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:33:41
User entered 'Yes (Y)'	Angie Northcott (b) (4) (b) (4)	12 Mar 2021 15:17:58

**US3082221**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:50
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:33:41
User entered '12 Mar 2021'	Angie Northcott (b) (4) (b) (4)	12 Mar 2021 15:17:58

US3082221

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:57:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:50
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:33:41
User entered 'Contact Made (CONTACT MADE)'	Angie Northcott (b) (4) (b) (4)	12 Mar 2021 15:17:58

US3082221

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:57:46

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:50
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:33:41
User entered empty.	Angie Northcott (b) (4) (b) (4)	12 Mar 2021 15:17:58

US3082221

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:57:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:50
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:33:49
User entered 'Yes (Y)'	Angie Northcott (b) (4) (b) (4)	12 Mar 2021 15:17:51

**US3082221**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:55:50
User entered 'I'	System	12 Mar 2021 15:17:51



**US3082221**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:41:19

US3082221

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:57:46

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:42
User entered '23 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:41:19

US3082221

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:57:46

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:41:19

**US3082221**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	23 Apr 2021 15:41:19

US3082221

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:41:27

US3082221

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:42
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:41:27

**US3082221**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:42
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:41:27

**US3082221**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 15:41:27



US3082221

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:42
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:41:27

**US3082221**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:42
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:41:27

US3082221

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:42
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:41:27

US3082221

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:42
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:41:27

**US3082221**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 15:41:27

US3082221

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:42
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:41:27

**US3082221**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 15:41:27

US3082221

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:42
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:41:27



**US3082221**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 15:41:27

US3082221

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:42
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:41:27

US3082221

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 15:41:27

US3082221

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:41:32

US3082221

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:42
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:41:32

US3082221

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:57:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:41:47

US3082221

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:57:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:42
User entered '23 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:41:47

US3082221

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:57:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:42
User entered '11:17'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:41:47



**US3082221**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '23 Apr 2021 11:17'	System	23 Apr 2021 15:41:47

US3082221

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:57:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:42:09

**US3082221**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 15:42:09

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:57:46

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 14-JAN-2021 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 14-JAN-2021 is missing in EDC. Kindly confirm if swab sample was collected if yes, consider initiating separate Covid-19 Assessment eCRF for 14-JAN-2021 & update swab data in the COVID Diagnostic Test eCRF, else clarify. ' (Site from DM). Query 'Per GCL Lab Reconciliation: Swab: Sample dated 14-JAN-2021 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 14-JAN-2021 is missing in EDC. Kindly confirm if swab sample was collected if yes, consider initiating separate Covid-19 Assessment eCRF for 14-JAN-2021 & update swab data in the COVID Diagnostic Test eCRF, else clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 04:13:15
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 14-JAN-2021 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 14-JAN-2021 is missing in EDC. Kindly confirm if swab sample was collected if yes, consider initiating separate Covid-19 Assessment eCRF for 14-JAN-2021 & update swab data in the COVID Diagnostic Test eCRF, else clarify. ' answered with 'updated' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	17 Mar 2021 11:57:50
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 14-JAN-2021 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 14-JAN-2021 is missing in EDC. Kindly confirm if swab sample was collected if yes, consider initiating separate Covid-19 Assessment eCRF for 14-JAN-2021 & update swab data in the COVID Diagnostic Test eCRF, else clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 10:04:36
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:58:44
User entered '13 Jan 2021'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:30

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:57:46

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:44
User entered '00:00'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:30

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:57:46

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered '13 Jan 2021 00:00'	System	15 Jan 2021 13:39:30

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:57:46

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User closed query ' Per ETRTR: Please consider to update Type of contact to Clinic Visit - Unscheduled /Safety Call as applicable.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 15:48:29
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:00
Query ' Per ETRTR: Please consider to update Type of contact to Clinic Visit - Unscheduled /Safety Call as applicable.' answered with 'updated' (Site from CRA).	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 13:16:15
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 13:16:09
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 13:16:09
User opened query ' Per ETRTR: Please consider to update Type of contact to Clinic Visit - Unscheduled /Safety Call as applicable.' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 21:19:55
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:58:44
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:30

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 21:57:46**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:44
User entered 'Yes (Y)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:30



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 1 (Day 1)'	Morgan Mathis (b) (4)	15 Jan 2021 13:39:53

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User closed query 'Per ETRTR: Please complete entries for Symptoms between 01Jan21 and 14Jan21.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 15:49:23
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
Query 'Per ETRTR: Please complete entries for Symptoms between 01Jan21 and 14Jan21.' answered with 'completed' (Site from CRA).	Ayssa Valente (b) (4)	09 Feb 2021 12:47:50
User opened query 'Per ETRTR: Please complete entries for Symptoms between 01Jan21 and 14Jan21.' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 21:23:34
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '1 Jan 2021'	Morgan Mathis (b) (4)	15 Jan 2021 13:39:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'l'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered empty.	System	15 Jan 2021 13:39:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:53



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:53



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:53

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:39:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 14 (Day 14)'	(b) (4) Morgan Mathis (b) (4)	15 Jan 2021 13:42:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '14 Jan 2021'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:42:53



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '0'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:42:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '96'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:42:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered '%'	System	15 Jan 2021 13:42:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '98.6' F	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:42:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:42:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:42:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:42:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:42:53



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'Mild (Mild)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:42:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:42:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:42:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:42:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:42:53

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'Mild (Mild)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:42:53

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:42:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:42:53



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'Moderate (Moderate)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:42:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'Moderate (Moderate)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:42:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:42:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:42:53

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 15 (Day 15)'	Ayssa Valente (b) (4)	18 Jan 2021 14:56:37

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:57:46**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '15 Jan 2021'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:56:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '0'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:56:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '93'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:56:37



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered '%'	System	18 Jan 2021 14:56:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '98.7' F	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:56:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:56:37

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:56:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:56:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:56:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:56:37

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:56:37



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:56:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'Mild (Mild)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:56:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:56:37

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:57:46**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'Mild (Mild)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:56:37

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:57:46**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:56:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:56:37

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 21:57:46**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'Mild (Mild)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:56:37

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:56:37



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:56:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 14:56:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 16 (Day 16)'	Ayssa Valente (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '16 Jan 2021'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '0'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '96'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:57:46**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered '%'	System	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '97.3' F	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'Mild (Mild)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 21:57:46**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'Mild (Mild)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 17 (Day 17)'	Ayssa Valente (b) (4)	18 Jan 2021 15:00:34

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:57:46**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '17 Jan 2021'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:57:46**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '0'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '98'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered '%'	System	18 Jan 2021 15:00:34

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '97.4' F	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'Mild (Mild)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34



**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:57:46**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 21:57:46**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'Mild (Mild)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:00:34

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 18 (Day 18)'	Erin Harrelson (b) (4)	19 Jan 2021 13:26:13

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '18 Jan 2021'	Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 13:26:13



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '0'	Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 13:26:13

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '96'	Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 13:26:13

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered '%'	System	19 Jan 2021 13:26:13

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '96' F	Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 13:26:13

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 13:26:13

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 13:26:13

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 13:26:13

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 13:26:13



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 13:26:13

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 13:26:13

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 13:26:13

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 13:26:13

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:57:46**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'Mild (Mild)'	Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 13:26:13

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'Mild (Mild)'	Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 13:26:13

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 21:57:46**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 13:26:13

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 13:26:13



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 13:26:13

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 13:26:13

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 13:26:13

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	19 Jan 2021 13:26:13

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 19 (Day 19)'	(b) (4) Morgan Mathis (b) (4)	20 Jan 2021 18:46:00

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '19 Jan 2021'	Morgan Mathis (b) (4) (b) (4)	20 Jan 2021 18:46:00

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '0'	Morgan Mathis (b) (4) (b) (4)	20 Jan 2021 18:46:00

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '99'	Morgan Mathis (b) (4) (b) (4)	20 Jan 2021 18:46:00



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered '%'	System	20 Jan 2021 18:46:00

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '96.0' F	Morgan Mathis (b) (4) (b) (4)	20 Jan 2021 18:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	20 Jan 2021 18:46:00

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	20 Jan 2021 18:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	20 Jan 2021 18:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	20 Jan 2021 18:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	20 Jan 2021 18:46:00

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	20 Jan 2021 18:46:00



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	20 Jan 2021 18:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	20 Jan 2021 18:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	20 Jan 2021 18:46:00

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	20 Jan 2021 18:46:00

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 21:57:46**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	20 Jan 2021 18:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	20 Jan 2021 18:46:00

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	20 Jan 2021 18:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	20 Jan 2021 18:46:00



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Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	20 Jan 2021 18:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	20 Jan 2021 18:46:00

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 20 (Day 20)'	Morgan Mathis (b) (4)	21 Jan 2021 13:45:42

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '20 Jan 2021'	Morgan Mathis (b) (4) (b) (4)	21 Jan 2021 13:45:42

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '0'	Morgan Mathis (b) (4) (b) (4)	21 Jan 2021 13:45:42

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '99'	Morgan Mathis (b) (4) (b) (4)	21 Jan 2021 13:45:42

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered '%'	System	21 Jan 2021 13:45:42

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '97.8' F	Morgan Mathis (b) (4) (b) (4)	21 Jan 2021 13:45:42



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Jan 2021 13:45:42

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Jan 2021 13:45:42

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Jan 2021 13:45:42

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Jan 2021 13:45:42

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Jan 2021 13:45:42

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Jan 2021 13:45:42

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Jan 2021 13:45:42

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Jan 2021 13:45:42



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Jan 2021 13:45:42

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (8)**

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Jan 2021 13:45:42

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Jan 2021 13:45:42

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Jan 2021 13:45:42

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Jan 2021 13:45:42

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Jan 2021 13:45:42

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Jan 2021 13:45:42

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	21 Jan 2021 13:45:42



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 21 (Day 21)'	Morgan Mathis (b) (4)	22 Jan 2021 14:08:18

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '21 Jan 2021'	Morgan Mathis (b) (4) (b) (4)	22 Jan 2021 14:08:18

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '0'	Morgan Mathis (b) (4) (b) (4)	22 Jan 2021 14:08:18

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '97'	Morgan Mathis (b) (4) (b) (4)	22 Jan 2021 14:08:18

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 21:57:46**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered '%'	System	22 Jan 2021 14:08:18

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '96.1' F	Morgan Mathis (b) (4) (b) (4)	22 Jan 2021 14:08:18

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	22 Jan 2021 14:08:18

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	22 Jan 2021 14:08:18



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	22 Jan 2021 14:08:18

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	22 Jan 2021 14:08:18

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	22 Jan 2021 14:08:18

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	22 Jan 2021 14:08:18

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	22 Jan 2021 14:08:18

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	22 Jan 2021 14:08:18

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	22 Jan 2021 14:08:18

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	22 Jan 2021 14:08:18



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	22 Jan 2021 14:08:18

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	22 Jan 2021 14:08:18

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'Mild (Mild)' reason for change: Data Entry Error	Morgan Mathis (b) (4)	22 Jan 2021 14:08:47
User entered 'None (None)'	(b) (4) Morgan Mathis (b) (4) (b) (4)	22 Jan 2021 14:08:18

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	22 Jan 2021 14:08:18

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	22 Jan 2021 14:08:18

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	22 Jan 2021 14:08:18

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 22 (Day 22)'	Erin Harrelson (b) (4)	25 Jan 2021 13:53:37

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (10)**

**Generated On: 11 Aug 2021 21:57:46**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '22 Jan 2021'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:53:37



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '0'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:53:37

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '99'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:53:37

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered '%'	System	25 Jan 2021 13:53:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '96.9' F	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:53:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:53:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:53:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:53:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:53:37



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:53:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:53:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:53:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:53:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:53:37

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:53:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:53:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:53:37



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:53:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:53:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:53:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:53:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 23 (Day 23)'	Erin Harrelson (b) (4)	25 Jan 2021 13:56:23

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '23 Jan 2021'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:56:23

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (11)**

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '0'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:56:23

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '99'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:56:23



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered '%'	System	25 Jan 2021 13:56:23

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '98.1' F	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:56:23

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:56:23

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:56:23

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:56:23

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:56:23

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:56:23

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:56:23



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:56:23

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:56:23

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:56:23

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:56:23

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:56:23

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:56:23

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:56:23

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:56:23



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:56:23

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Erin Harrelson (b) (4) (b) (4)	25 Jan 2021 13:56:23

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 24 (Day 24)'	(b) (4) Morgan Mathis (b) (4)	26 Jan 2021 13:43:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '24 Jan 2021'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:43:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '0'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:43:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '99'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:43:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered '%'	System	26 Jan 2021 13:43:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '97.9' F	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:43:15



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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:43:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:43:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:43:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:43:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:43:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:43:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:43:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:43:15



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:43:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:43:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:43:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:43:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:43:15

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:43:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (12)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:43:15

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Form: Symptom Log (12)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:43:15



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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 25 (Day 25)'	Morgan Mathis (b) (4)	26 Jan 2021 13:44:19

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Folder: Covid-19 Assessment 13 Jan 2021

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '25 Jan 2021'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:44:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '0'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:44:19

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Folder: Covid-19 Assessment 13 Jan 2021

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '99'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:44:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered '%'	System	26 Jan 2021 13:44:19

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Folder: Covid-19 Assessment 13 Jan 2021

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '96.1' F	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:44:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:44:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:44:19



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:44:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:44:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:44:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:44:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:44:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:44:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:44:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:44:19



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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:44:19

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Folder: Covid-19 Assessment 13 Jan 2021

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:44:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:44:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:44:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:44:19

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (13)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:44:19

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 26 (Day 26)'	Morgan Mathis (b) (4)	28 Jan 2021 13:35:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '26 Jan 2021'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:35:07



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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '0'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:35:07

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '99'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:35:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered '%'	System	28 Jan 2021 13:35:07

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Folder: Covid-19 Assessment 13 Jan 2021

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '98.1' F	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:35:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:35:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:35:07

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:35:07

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:35:07



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:35:07

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:35:07

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:35:07

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:35:07

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:35:07

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:35:07

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:35:07

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:35:07



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:35:07

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:35:07

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:35:07

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:35:07

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 27 (Day 27)'	(b) (4) Morgan Mathis (b) (4)	28 Jan 2021 13:36:11

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '27 Jan 2021'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:36:11

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '0'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:36:11

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '99'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:36:11



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered '%'	System	28 Jan 2021 13:36:11

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered '97.9' F	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:36:11

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:36:11

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:36:11

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:36:11

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:36:11

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:36:11

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:36:11



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:36:11

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:36:11

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:36:11

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:36:11

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:36:11

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:36:11

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:36:11

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:36:11



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:36:11

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:05
User entered 'None (None)'	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:36:11

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 2 (Day 2)'	Ayssa Valente (b) (4)	09 Feb 2021 12:45:15

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered '2 Jan 2021'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered 'l'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:15

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered empty.	System	09 Feb 2021 12:45:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:15



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:15

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:15

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:15

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:15

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:15

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:15

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:15

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:15



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:15

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:15

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:15

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:15

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:15

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:15

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:15

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:15



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 3 (Day 3)'	Ayssa Valente (b) (4)	09 Feb 2021 12:45:28

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered '3 Jan 2021'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:28

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered 'l'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:28

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:28

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered empty.	System	09 Feb 2021 12:45:28

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:28

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:28

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:28



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:28

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:28

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:28

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:28

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:28

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:28

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:28

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:28



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:28

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:28

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:28

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:28

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:28

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:28

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 4 (Day 4)'	Ayssa Valente (b) (4)	09 Feb 2021 12:45:38

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered '4 Jan 2021'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:38



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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered 'l'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:38

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:38

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered empty.	System	09 Feb 2021 12:45:38

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:38

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:38

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:38

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:38

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:38



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:38

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:38

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:38

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:38

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:38

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:38

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:38

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:38



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:38

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:38

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:38

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:38

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 5 (Day 5)'	Ayssa Valente (b) (4)	09 Feb 2021 12:45:49

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Symptom Log (19)**

**Generated On: 11 Aug 2021 21:57:46**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered '5 Jan 2021'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:49

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered 'I'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:49

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:49



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered empty.	System	09 Feb 2021 12:45:49

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:49

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:49

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:49

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:49

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:49

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:49

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:49



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:49

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:49

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:49

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:49

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:49

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:49

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:49

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:49



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:49

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:45:49

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 6 (Day 6)'	Ayssa Valente (b) (4)	09 Feb 2021 12:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered '6 Jan 2021'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	28 Apr 2021 22:02:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:31:47
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 13 Jan 2021 symptom log on log line 20. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 11:20:03
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 13 Jan 2021 symptom log on log line 20. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'updated to not done' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	20 Apr 2021 15:01:04
DataPoint Un-verified.	Erin Harrelson (b) (4) (b) (4)	20 Apr 2021 14:59:49
Signature has been broken.	Erin Harrelson (b) (4) (b) (4)	20 Apr 2021 14:59:49
User entered '1' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	20 Apr 2021 14:59:49
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 13 Jan 2021 symptom log on log line 20. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 07:14:10
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered '0'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered empty.	System	09 Feb 2021 12:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:00



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:00



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:00

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (20)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:00



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 7 (Day 7)'	Ayssa Valente (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered '7 Jan 2021'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered 'l'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered empty.	System	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (21)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 8 (Day 8)'	Ayssa Valente (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered '8 Jan 2021'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered 'l'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered empty.	System	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (22)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:35

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 9 (Day 9)'	Ayssa Valente (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered '9 Jan 2021'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered 'l'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered empty.	System	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (23)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 10 (Day 10)'	Ayssa Valente (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered '10 Jan 2021'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered 'l'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered empty.	System	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (24)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:46:54



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 11 (Day 11)'	(b) (4) Ayssa Valente (b) (4)	09 Feb 2021 12:47:05

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered '11 Jan 2021'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:05

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered 'l'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:05

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:05

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered empty.	System	09 Feb 2021 12:47:05

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:05

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:05

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:05



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:05

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:05

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:05

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:05

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:05

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:05

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:05

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:05



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:05

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:05

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:05

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:05

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:05

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (25)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:05

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 12 (Day 12)'	Ayssa Valente (b) (4)	09 Feb 2021 12:47:16

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered '12 Jan 2021'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:16



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered 'l'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:16

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:16

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered empty.	System	09 Feb 2021 12:47:16

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:16

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:16

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:16

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:16

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:16



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:16

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:16

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:16

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:16

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:16

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:16

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:16

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:16



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:16

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:16

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:16

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (26)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:16

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Day 13 (Day 13)'	(b) (4) Ayssa Valente (b) (4)	09 Feb 2021 12:47:27

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered '13 Jan 2021'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:27

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered 'I'	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:27

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:27



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered empty.	System	09 Feb 2021 12:47:27

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:27

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:27

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:27

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:27

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:27

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:27

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:27



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:27

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:27

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:27

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:27

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:27

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:27

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:27

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:27



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:27

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (27)

Generated On: 11 Aug 2021 21:57:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:24:37
User entered empty.	Ayssa Valente (b) (4) (b) (4)	09 Feb 2021 12:47:27

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:57:46

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:26:03
DataPoint Un-verified.	Ayssa Valente (b) (4)	17 Mar 2021 11:53:53
Signature has been broken.	(b) (4) Ayssa Valente (b) (4)	17 Mar 2021 11:53:53
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	17 Mar 2021 11:53:53
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:24
User entered '8 Jan 2021'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:43:37

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 21:57:46**

[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 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:24
User entered 'Yes (Y)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:43:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:57:46

[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 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:24
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)	18 Jan 2021 05:40:25
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 'yes confirmed' (Site from System).	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:43:54
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	15 Jan 2021 13:43:37
User entered 'Yes (Y)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:43:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:57:46

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:26:03
DataPoint Un-verified.	Ayssa Valente (b) (4)	17 Mar 2021 11:53:53
Signature has been broken.	(b) (4) Ayssa Valente (b) (4)	17 Mar 2021 11:53:53
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	17 Mar 2021 11:53:53
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 08JAN2021 under Covid-19 Assessment in EDC, however same is reported as Participant Decision Visit / OL-D1 in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 11:23:52
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 08JAN2021 under Covid-19 Assessment in EDC, however same is reported as Participant Decision Visit / OL-D1 in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' answered with 'The subject tested positive from their OL-D1 swab' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	16 Feb 2021 12:49:27
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 08JAN2021 under Covid-19 Assessment in EDC, however same is reported as Participant Decision Visit / OL-D1 in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 08:31:06
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Re-query: Swab sample dated 08JAN2021 is reported under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 09:28:32

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:57:46

[Date of Test](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Re-query: Swab sample dated 08JAN2021 is reported under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please amend GCL or Preclarus as appropriate. Thank you.' answered with 'this swab was from the patients Open label decision visit' (Site from DM).	Ayssa Valente (b) (4)	08 Feb 2021 13:19:51
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Re-query: Swab sample dated 08JAN2021 is reported under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 08:20:20
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:59:24
User entered '8 Jan 2021'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:43:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:57:46

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:24
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:43:37



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:57:46

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:24
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:43:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:57:46

[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 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:24
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:43:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:57:46

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:24
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:43:37

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:57:46

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:24
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:43:37

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User entered 'I'	System	15 Jan 2021 13:43:37

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:46

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:46

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07



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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:46

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:46

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 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:46

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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Generated On: 11 Aug 2021 21:57:46

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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Folder: Covid-19 Assessment 13 Jan 2021

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Generated On: 11 Aug 2021 21:57:46

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:09
User closed query 'Per CDM RQ: Start Date, End Date and Oxygen Saturation in the fields below are also required when this field is recorded as "Yes". Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 12:31:34
Query 'Per CDM RQ: Start Date, End Date and Oxygen Saturation in the fields below are also required when this field is recorded as "Yes". Please update as appropriate.' answered with 'added dates' (Site from DM).	Alice Cipollini (b) (4) (b) (4)	31 Mar 2021 18:16:00
User opened query 'Per CDM RQ: Start Date, End Date and Oxygen Saturation in the fields below are also required when this field is recorded as "Yes". Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 11:57:44
User closed query 'Per CDM: Per sponsor review, Symptom Log 15 Jan 2021 records SpO2 of 93%, however field is recorded as no. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 11:57:44
Query 'Per CDM: Per sponsor review, Symptom Log 15 Jan 2021 records SpO2 of 93%, however field is recorded as no. Please review and reconcile.' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	29 Mar 2021 17:31:59
DataPoint Un-verified.	Erin Harrelson (b) (4) (b) (4)	29 Mar 2021 17:31:44
Signature has been broken.	Erin Harrelson (b) (4) (b) (4)	29 Mar 2021 17:31:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Erin Harrelson (b) (4) (b) (4)	29 Mar 2021 17:31:44
User opened query 'Per CDM: Per sponsor review, Symptom Log 15 Jan 2021 records SpO2 of 93%, however field is recorded as no. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 17:14:13
User signature succeeded.	Barton Williams (b) (4) (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:09
DataPoint Un-verified.	Alice Cipollini (b) (4)	31 Mar 2021 18:15:42
Signature has been broken.	(b) (4) Alice Cipollini (b) (4)	31 Mar 2021 18:15:42
User entered '15 Jan 2021' reason for change: Data Entry Error	(b) (4) Alice Cipollini (b) (4)	31 Mar 2021 18:15:42
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4)	20 Jan 2021 14:08:07
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:46

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:09
DataPoint Un-verified.	Alice Cipollini (b) (4)	31 Mar 2021 18:15:42
Signature has been broken.	(b) (4) Alice Cipollini (b) (4)	31 Mar 2021 18:15:42
User entered '15 Jan 2021' reason for change: Data Entry Error	(b) (4) Alice Cipollini (b) (4)	31 Mar 2021 18:15:42
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4)	20 Jan 2021 14:08:07
	(b) (4)	



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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:50:09
DataPoint Un-verified.	Alice Cipollini (b) (4)	31 Mar 2021 18:15:42
Signature has been broken.	(b) (4) Alice Cipollini (b) (4)	31 Mar 2021 18:15:42
User entered '93' reason for change: Data Entry Error	(b) (4) Alice Cipollini (b) (4)	31 Mar 2021 18:15:42
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4)	20 Jan 2021 14:08:07
	(b) (4)	

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Form: Covid-19 Severity Assessment

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:46

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07



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Generated On: 11 Aug 2021 21:57:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:46

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:46

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07



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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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Folder: Covid-19 Assessment 13 Jan 2021

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Generated On: 11 Aug 2021 21:57:46

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07



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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:46

[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:46

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:46

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

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**Generated On: 11 Aug 2021 21:57:46**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:46

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

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**Generated On: 11 Aug 2021 21:57:46**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:46

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07



**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:46

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:46

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:46

[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 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07

**US3082221**

**Folder: Covid-19 Assessment 13 Jan 2021**

**Form: Covid-19 Severity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:59:36
User entered empty.	Ayssa Valente (b) (4) (b) (4)	20 Jan 2021 14:08:07



US3082221

Folder: Covid-19 Assessment 13 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 21:57:46

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:43:59
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:26:17
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
User entered 'No (N)'	(b) (4) Ayssa Valente (b) (4) (b) (4)	03 Mar 2021 15:55:09

**US3082221**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:48:46

**US3082221**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:17
User entered 'Yes (Y)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:48:46

**US3082221**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:17
User entered '16 Jan 2021'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:48:46

**US3082221**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:48:46

**US3082221**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:17
User entered 'Yes (Y)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:48:46

**US3082221**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:17
User entered '18 Jan 2021'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:48:46

US3082221

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:57:46

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession #1F635864282 is reported with 20JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 07:42:11
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession #1F635864282 is reported with 20JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you' answered with 'updated' (Site from DM).	Ayssa Valente (b) (4)	04 Feb 2021 13:52:28
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 7 sample with Accession #1F635864282 is reported with 20JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 06:19:16
User accepted default value 'Day 7 (Day 7)'	Morgan Mathis (b) (4)	26 Jan 2021 13:48:46



**US3082221**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 21:57:46**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:25:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Un-verified.	Ayssa Valente (b) (4)	04 Feb 2021 13:52:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Ayssa Valente (b) (4)	04 Feb 2021 13:52:51
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:58:17
User entered 'No (N)'	Morgan Mathis (b) (4)	26 Jan 2021 13:48:46

**US3082221**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 21:57:46**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:25:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Un-verified.	Ayssa Valente (b) (4)	04 Feb 2021 13:52:51
User entered '20 Jan 2021' reason for change: Data Entry Error	Ayssa Valente (b) (4)	04 Feb 2021 13:52:51
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:58:17
User entered empty.	Morgan Mathis (b) (4)	26 Jan 2021 13:48:46

**US3082221**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 21:57:46**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:48:46

US3082221

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:57:46

Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:25:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F640530514 is reported with 22JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 07:42:14
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F640530514 is reported with 22JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you' answered with 'updated' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	04 Feb 2021 13:53:28
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	04 Feb 2021 13:53:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	04 Feb 2021 13:53:20
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 9 sample with Accession # 1F640530514 is reported with 22JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 06:20:31
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:58:17
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:48:46

**US3082221**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 21:57:46**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:25:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Un-verified.	Ayssa Valente (b) (4)	04 Feb 2021 13:53:20
User entered '22 Jan 2021' reason for change: Data Entry Error	Ayssa Valente (b) (4)	04 Feb 2021 13:53:20
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:58:17
User entered empty.	Morgan Mathis (b) (4)	26 Jan 2021 13:48:46

**US3082221**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 21:57:46**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:48:46

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:57:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:25:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F633747088 is reported with 27JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 07:34:02
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F633747088 is reported with 27JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you' answered with 'updated' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	04 Feb 2021 13:53:49
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	04 Feb 2021 13:53:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	04 Feb 2021 13:53:41
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F633747088 is reported with 27JAN2021 Date of Collection however in EDC is marked as No. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend EDC or Preclarus Thank you' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 06:21:22
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:58:17
User entered 'No (N)' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	28 Jan 2021 13:41:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Jan 2021 12:18:06
Query 'Data is required. Please complete.' answered with 'not done yet' (Site from System).	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:48:54
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 13:48:46
User entered empty.	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:48:46

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EAB) (1725)

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 21:57:46**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:25:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Un-verified.	Ayssa Valente (b) (4)	04 Feb 2021 13:53:41
User entered '27 Jan 2021' reason for change: Data Entry Error	Ayssa Valente (b) (4)	04 Feb 2021 13:53:41
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:58:17
User entered empty.	Morgan Mathis (b) (4)	26 Jan 2021 13:48:46



US3082221

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:57:46

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Please complete.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 15:50:00
Query 'Per ETRTR: Please complete.' answered with 'completed' (Site from CRA).	Ayssa Valente (b) (4)	09 Feb 2021 13:16:51
User opened query 'Per ETRTR: Please complete.' (Site from CRA).	(b) (4)	08 Feb 2021 21:17:29
User accepted default value 'Day 21 (Day 21)'	Morgan Mathis (b) (4)	26 Jan 2021 13:48:46

US3082221

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:57:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:25:59
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F651066522 is reported with 03FEB2021 Date of Collection however in EDC is No. Please review the Accession # in Preclarus and confirm the correct date and amend EDC or Preclarus. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:55:43
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F651066522 is reported with 03FEB2021 Date of Collection however in EDC is No. Please review the Accession # in Preclarus and confirm the correct date and amend EDC or Preclarus. Thank you.' answered with 'updated per PPD' (Site from DM).	Alice Cipollini (b) (4)	19 Feb 2021 14:04:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Alice Cipollini (b) (4)	19 Feb 2021 14:04:40
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F651066522 is reported with 03FEB2021 Date of Collection however in EDC is No. Please review the Accession # in Preclarus and confirm the correct date and amend EDC or Preclarus. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 07:44:26
DataPoint Un-verified.	Ayssa Valente (b) (4)	09 Feb 2021 13:16:33
User entered 'No (N)' reason for change: Data Entry Error	Ayssa Valente (b) (4)	09 Feb 2021 13:16:33
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:58:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Jan 2021 12:18:10
Query 'Data is required. Please complete.' answered with 'not done yet' (Site from System).	Morgan Mathis (b) (4)	26 Jan 2021 13:48:59
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 13:48:46
User entered empty.	Morgan Mathis (b) (4)	26 Jan 2021 13:48:46

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 21:57:46**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:25:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Un-verified.	Alice Cipollini (b) (4)	19 Feb 2021 14:04:40
User entered '03 Feb 2021' reason for change: Data Entry Error	Alice Cipollini (b) (4)	19 Feb 2021 14:04:40
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:58:17
User entered empty.	Morgan Mathis (b) (4)	26 Jan 2021 13:48:46

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 21:57:46**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:48:46

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:57:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:25:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:27:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 14:27:38
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:58:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Jan 2021 12:18:14
Query 'Data is required. Please complete.' answered with 'not done yet' (Site from System).	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:49:05
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 13:48:46
User entered empty.	Morgan Mathis (b) (4) (b) (4)	26 Jan 2021 13:48:46

**US3082221**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 21:57:46**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:25:59
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 14:27:38
User entered '11 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 14:27:38
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:58:17
User entered empty.	Morgan Mathis (b) (4)	26 Jan 2021 13:48:46

**US3082221**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:53:50
User entered 'Yes (Y)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:52:00

**US3082221**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:53:50
User entered '14 Jan 2021'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:52:00



**US3082221**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[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 16:08:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:53:50
User entered 'Home (Home)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:52:00

**US3082221**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User entered 'SICKD1'	System	15 Jan 2021 13:52:00

**US3082221**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:54:12
User entered 'Yes (Y)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:53:15

**US3082221**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:54:12
User entered '14 Jan 2021'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:53:15

**US3082221**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:54:12
User entered '00:00'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:53:15

**US3082221**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User entered '14 Jan 2021 00:00'	System	15 Jan 2021 13:53:15

US3082221

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:54:12
User entered missing code ND - Not Done.	Morgan Mathis (b) (4)	15 Jan 2021 13:53:15
DataPoint set to visible.	(b) (4) System	15 Jan 2021 13:52:00

**US3082221**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:54:12
User entered missing code ND - Not Done.	Morgan Mathis (b) (4)	15 Jan 2021 13:53:15
DataPoint set to visible.	(b) (4) System	15 Jan 2021 13:52:00



US3082221

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:54:12
User entered '98.4' F reason for change: Data Entry Error	Morgan Mathis (b) (4)	15 Jan 2021 14:09:23
User entered '98.6' F	Morgan Mathis (b) (4)	15 Jan 2021 13:53:15

**US3082221**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:54:12
User entered 'Oral (Oral)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:53:15

**US3082221**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:54:12
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:53:15

**US3082221**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:54:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Morgan Mathis (b) (4)	15 Jan 2021 14:09:23
User entered '92'	(b) (4) Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:53:15

**US3082221**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User entered 'bpm'	System	15 Jan 2021 13:53:15

US3082221

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:54:12
User entered '14' reason for change: Data Entry Error	Morgan Mathis (b) (4)	15 Jan 2021 14:09:23
User entered missing code ND - Not Done.	(b) (4) Morgan Mathis (b) (4)	15 Jan 2021 13:53:15

**US3082221**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User entered 'breaths/min'	System	15 Jan 2021 13:53:15

US3082221

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:54:12
User entered '127' reason for change: Data Entry Error	Morgan Mathis (b) (4)	15 Jan 2021 14:09:23
User entered missing code ND - Not Done.	(b) (4) Morgan Mathis (b) (4)	15 Jan 2021 13:53:15



US3082221

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User entered 'mmHg'	System	15 Jan 2021 13:53:15

US3082221

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:54:12
User entered '85' reason for change: Data Entry Error	Morgan Mathis (b) (4)	15 Jan 2021 14:09:23
User entered missing code ND - Not Done.	(b) (4) Morgan Mathis (b) (4)	15 Jan 2021 13:53:15

**US3082221**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User entered 'mmHg'	System	15 Jan 2021 13:53:15

**US3082221**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49

**US3082221**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49

US3082221

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:51
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:53:24

**US3082221**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:57:46**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:51
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:53:24

US3082221

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:57:46

[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 16:08:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:57:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Morgan Mathis (b) (4)	15 Jan 2021 14:10:00
User entered 'No (N)'	(b) (4) Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 13:55:53



US3082221

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:57:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:08:49
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User closed query 'Per Lab Recon: SARS-COV2: Sample dated 14 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 09:54:58
' (Site from DM). Query 'Per Lab Recon: SARS-COV2: Sample dated 14 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.	Alice Cipollini (b) (4) (b) (4)	03 Feb 2021 15:29:03
' answered with 'Sample has been collected and shipped. In our records for PPD the samples have been received and results have been reported.' (Site from DM). User opened query 'Per Lab Recon: SARS-COV2: Sample dated 14 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.	(b) (4), (b) (6)	29 Jan 2021 09:01:01
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:57:58

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US3082221

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:57:46

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '14 Jan 2021' reason for change: Data Entry Error	Morgan Mathis (b) (4)	15 Jan 2021 14:10:00
User entered empty.	Morgan Mathis (b) (4)	15 Jan 2021 13:55:53

**US3082221**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:26:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:26:26

**US3082221**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:26:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:26:26

US3082221

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:57:46

[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 16:17:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:26:47
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:26:26

**US3082221**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User entered 'SICKD28'	System	11 Feb 2021 14:26:26

US3082221

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:27:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:27:06

US3082221

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:27:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:27:06



**US3082221**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:27:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered '08:15'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:27:06

US3082221

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User entered '11 Feb 2021 08:15'	System	11 Feb 2021 14:27:06

**US3082221**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:27:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered '63.0' in	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:27:06
DataPoint set to visible.	System	11 Feb 2021 14:26:26

US3082221

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:27:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered '167.8' lb	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:27:06
DataPoint set to visible.	System	11 Feb 2021 14:26:26

US3082221

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:27:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:27:06

US3082221

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:27:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:27:06

US3082221

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:27:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:27:06

**US3082221**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:27:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered '86'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:27:06



**US3082221**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User entered 'bpm'	System	11 Feb 2021 14:27:06

US3082221

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:27:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered '18'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:27:06

**US3082221**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User entered 'breaths/min'	System	11 Feb 2021 14:27:06

US3082221

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:27:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered '129'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:27:06

**US3082221**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User entered 'mmHg'	System	11 Feb 2021 14:27:06

US3082221

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:27:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered '93'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:27:06

**US3082221**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User entered 'mmHg'	System	11 Feb 2021 14:27:06

US3082221

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27



US3082221

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27

US3082221

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:27:16
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:27:13

US3082221

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:27:16
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:27:13

US3082221

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:57:46

[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 16:17:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:27:30
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:27:21

US3082221

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:57:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:27:30
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:27:21

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 17:54:59

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:42
User entered '8 Jan 2021'	(b) (4), (b) (6)	08 Jan 2021 17:54:59

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:42
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Jan 2021 17:54:59



**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 17:54:59

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:57:46**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:00
User entered '6 Jan 2021'	(b) (4), (b) (6)	08 Jan 2021 17:55:13

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:57:46**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:19:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
User entered '0'	(b) (4) Erin Harrelson (b) (4)	12 Apr 2021 14:38:39
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 19:01:40

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:57:46**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 17:55:13

US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:57:46

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:19:46
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:08:06
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4) (b) (4)	12 Apr 2021 14:39:02
User entered 'Amendment 6 or later (Amendment 6 or later)'	Erin Harrelson (b) (4) (b) (4)	12 Apr 2021 14:38:39
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	10 Apr 2021 14:52:48
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:01:40

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:57:46**

[Date of unblinding \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:00
User entered '8 Jan 2021'	(b) (4), (b) (6)	08 Jan 2021 17:55:13

US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:57:46

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:00
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	08 Jan 2021 17:55:13

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:57:46**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:00
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 14:35:40
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	08 Jan 2021 17:55:13



**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:57:46**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:00
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 14:35:40
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	08 Jan 2021 17:55:13

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:57:46**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 17:55:13

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:57:46**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered '1'	System	08 Jan 2021 17:55:13

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:57:46**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'I'	System	08 Jan 2021 17:55:13

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:57:46**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered '63.0' in	(b) (4), (b) (6)	08 Jan 2021 17:57:46

US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:57:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered '170.2' lb	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:57:46**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered '30.21262'	System	08 Jan 2021 17:57:46
DataPoint set to visible.	System	08 Jan 2021 17:55:13

US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:57:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered '63.0' in	(b) (4), (b) (6)	08 Jan 2021 17:57:46



**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:57:46**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered '170.2' lb	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:57:46**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered '30.21262'	System	08 Jan 2021 17:57:46
DataPoint set to visible.	System	08 Jan 2021 17:55:13

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered '8 Jan 2021'	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered '11:33'	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered '8 Jan 2021 11:33'	System	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered '98.7' F	(b) (4), (b) (6)	08 Jan 2021 17:57:46



**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered '83'	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'bpm'	System	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered '18'	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'breaths/min'	System	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered '128'	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'mmHg'	System	08 Jan 2021 17:57:46



**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered '81'	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'mmHg'	System	08 Jan 2021 17:57:46

US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:57:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered '63.0' in	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:57:46**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered '170.2' lb	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:57:46**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered '30.21262'	System	08 Jan 2021 17:57:46
DataPoint set to visible.	System	08 Jan 2021 17:55:13

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered '8 Jan 2021'	(b) (4), (b) (6)	08 Jan 2021 17:57:46



**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered '11:51'	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered '8 Jan 2021 11:51'	System	08 Jan 2021 17:57:46

US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered '98.8' F	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered '76'	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'bpm'	System	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered '17'	(b) (4), (b) (6)	08 Jan 2021 17:57:46



**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'breaths/min'	System	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered '109'	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'mmHg'	System	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:22
User entered '75'	(b) (4), (b) (6)	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'mmHg'	System	08 Jan 2021 17:57:46

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:57:46**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 17:58:10

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:57:46**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:39
User entered '8 Jan 2021'	(b) (4), (b) (6)	08 Jan 2021 17:58:10

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 17:58:55



**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:48
User entered '8 Jan 2021'	(b) (4), (b) (6)	08 Jan 2021 17:58:55

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:48
User entered 'Urine (URINE)'	(b) (4), (b) (6)	08 Jan 2021 17:58:55

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:48
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	08 Jan 2021 17:58:55

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:48
User entered 'No (N)'	(b) (4), (b) (6)	08 Jan 2021 17:58:55

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:48
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 17:58:55

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:05:48
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 17:58:55

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered empty.	System	08 Jan 2021 17:58:55

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:57:46**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 17:59:18



**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:57:46**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:17
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 17:59:18

US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

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)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:17
User entered empty.	(b) (4), (b) (6)	08 Jan 2021 17:59:18

US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'mRNA-1273'	System	08 Jan 2021 17:59:18
DataPoint set to visible.	System	08 Jan 2021 17:55:13

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:57:46**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:17
User entered '8 Jan 2021'	(b) (4), (b) (6)	08 Jan 2021 17:59:18

US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:17
User entered '12:20'	(b) (4), (b) (6)	08 Jan 2021 17:59:18

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:57:46**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered '8 Jan 2021 12:20'	System	08 Jan 2021 17:59:18

US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:17
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	08 Jan 2021 17:59:18

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:57:46**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:06:17
User entered 'ONCE'	System	08 Jan 2021 17:59:18



US3082221

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'INTRAMUSCULAR'	System	08 Jan 2021 17:59:18

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 17:59:31

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:43
User entered '8 Jan 2021'	(b) (4), (b) (6)	08 Jan 2021 17:59:31

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:43
User entered '11:55'	(b) (4), (b) (6)	08 Jan 2021 17:59:31

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered '8 Jan 2021 11:55'	System	08 Jan 2021 17:59:31

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:57:46**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 17:59:41

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:57:46**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:06:59
User entered '8 Jan 2021'	(b) (4), (b) (6)	08 Jan 2021 17:59:41

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:57:46**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:59
User entered '11:53'	(b) (4), (b) (6)	08 Jan 2021 17:59:41



**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:57:46**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered '8 Jan 2021 11:53'	System	08 Jan 2021 17:59:41

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Jan 2021 17:59:48

**US3082221**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'I'	System	08 Jan 2021 17:59:48

**US3082221**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:29:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 14:29:53

**US3082221**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:29:30
User entered '18 Jan 2021'	(b) (4), (b) (6)	11 Feb 2021 14:29:53

**US3082221**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:29:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Feb 2021 14:29:53

**US3082221**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:29:30
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 14:29:53

US3082221

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:57:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:30:36
DataPoint Un-verified.	(b) (4), (b) (6)	24 Feb 2021 19:30:17
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:30:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 14:29:58



**US3082221**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'I'	System	11 Feb 2021 14:29:58

**US3082221**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered '1'	System	11 Feb 2021 14:29:58
DataPoint set to visible.	System	11 Feb 2021 14:29:58

**US3082221**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:32:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 14:30:08

**US3082221**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:32:00
User entered '11 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 14:30:08

**US3082221**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:32:00
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Feb 2021 14:30:08

**US3082221**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'OLD29'	System	11 Feb 2021 14:30:08

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:33:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 14:34:04



US3082221

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:33:02
User entered '11 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:33:02
User entered '08:15'	(b) (4), (b) (6)	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered '11 Feb 2021 08:15'	System	11 Feb 2021 14:34:04

US3082221

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 19:33:02
User entered '98.7' F	(b) (4), (b) (6)	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:33:02
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:33:02
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:33:02
User entered '86'	(b) (4), (b) (6)	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'bpm'	System	11 Feb 2021 14:34:04



**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:33:02
User entered '18'	(b) (4), (b) (6)	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'breaths/min'	System	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:33:02
User entered '129'	(b) (4), (b) (6)	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'mmHg'	System	11 Feb 2021 14:34:04

US3082221

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:33:02
User entered '93'	(b) (4), (b) (6)	11 Feb 2021 14:34:04

US3082221

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'mmHg'	System	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:33:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 14:34:04



**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:33:02
User entered '11 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:33:02
User entered '09:24'	(b) (4), (b) (6)	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered '11 Feb 2021 09:24'	System	11 Feb 2021 14:34:04

US3082221

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:33:02
User entered '98.2' F	(b) (4), (b) (6)	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:33:02
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:33:02
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:33:02
User entered '90'	(b) (4), (b) (6)	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'bpm'	System	11 Feb 2021 14:34:04



US3082221

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:33:02
User entered '17'	(b) (4), (b) (6)	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'breaths/min'	System	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:33:02
User entered '113'	(b) (4), (b) (6)	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'mmHg'	System	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 19:33:02
User entered '77'	(b) (4), (b) (6)	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'mmHg'	System	11 Feb 2021 14:34:04

**US3082221**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:57:46**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:27:19
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:30:18

**US3082221**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:57:46**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:27:19
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:30:18



**US3082221**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:28:00
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:30:48

**US3082221**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:28:00
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:30:48

**US3082221**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:28:00
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:30:48

**US3082221**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:28:00
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:30:48

US3082221

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:57:46

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:28:00
User closed query 'Per CDM: Was FSH sample collected? =No, however the date and time of collection is recorded. Kindly review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 12:21:07
Query 'Per CDM: Was FSH sample collected? =No, however the date and time of collection is recorded. Kindly review and update accordingly. Thank you.' answered with 'updated' (Site from DM).	Erin Harrelson (b) (4)	19 Mar 2021 11:57:32
User opened query 'Per CDM: Was FSH sample collected? =No, however the date and time of collection is recorded. Kindly review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 06:26:02
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'No (N)'	(b) (4), (b) (6)	11 Feb 2021 14:30:48

US3082221

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:57:46

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:28:00
Signature has been broken.	Erin Harrelson (b) (4)	19 Mar 2021 11:57:43
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Mar 2021 11:57:43
User signature succeeded.	(b) (4) Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:30:48

US3082221

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:57:46

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:28:00
Signature has been broken.	Erin Harrelson (b) (4)	19 Mar 2021 11:57:43
User entered empty; reason for change Data Entry Error	(b) (4) Erin Harrelson (b) (4)	19 Mar 2021 11:57:43
User signature succeeded.	(b) (4) Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered '08:41'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:30:48

**US3082221**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered empty.	System	19 Mar 2021 11:57:43
User entered '11 Feb 2021 08:41'	System	11 Feb 2021 14:30:48



**US3082221**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:57:46**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:28:36
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:32:01

**US3082221**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:57:46**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:28:36
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:32:01

US3082221

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

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)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:28:36
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:32:01

US3082221

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'mRNA-1273'	System	11 Feb 2021 14:32:01
DataPoint set to visible.	System	11 Feb 2021 14:29:58

US3082221

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:28:36
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:32:01

**US3082221**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:57:46**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:28:36
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered '08:54'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:32:01

US3082221

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered '11 Feb 2021 08:54'	System	11 Feb 2021 14:32:01

US3082221

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:28:36
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:32:01



US3082221

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:28:36
User entered 'ONCE'	System	11 Feb 2021 14:32:01

US3082221

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'INTRAMUSCULAR'	System	11 Feb 2021 14:32:01

**US3082221**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:28:45
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:32:06

**US3082221**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'I'	System	11 Feb 2021 14:32:06

**US3082221**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:29:56
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Yes (Y)'	(b) (4) Erin Harrelson (b) (4) (b) (4)	18 Feb 2021 18:07:41

**US3082221**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:29:56
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered '18 Feb 2021'	(b) (4) Erin Harrelson (b) (4) (b) (4)	18 Feb 2021 18:07:41

**US3082221**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:29:56
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erin Harrelson (b) (4) (b) (4)	18 Feb 2021 18:07:41

**US3082221**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:29:56
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered empty.	(b) (4) Erin Harrelson (b) (4) (b) (4)	18 Feb 2021 18:07:41



**US3082221**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:30:06
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered 'Yes (Y)'	(b) (4) Erin Harrelson (b) (4) (b) (4)	18 Feb 2021 18:07:45

**US3082221**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'I'	System	18 Feb 2021 18:07:45

**US3082221**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:30:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 13:40:48

**US3082221**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:30:32
User entered '17 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 13:40:48

**US3082221**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:30:32
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Mar 2021 13:40:48

**US3082221**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'OLD57'	System	17 Mar 2021 13:40:48

**US3082221**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:30:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 13:41:18

**US3082221**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:30:39
User entered '17 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 13:41:18



**US3082221**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:30:39
User entered '09:09'	(b) (4), (b) (6)	17 Mar 2021 13:41:18

**US3082221**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered '17 Mar 2021 09:09'	System	17 Mar 2021 13:41:18

**US3082221**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:30:39
User entered '98.6' F	(b) (4), (b) (6)	17 Mar 2021 13:41:18

**US3082221**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:30:39
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Mar 2021 13:41:18

**US3082221**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:30:39
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 13:41:18

**US3082221**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:30:39
User entered '78'	(b) (4), (b) (6)	17 Mar 2021 13:41:18

**US3082221**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'bpm'	System	17 Mar 2021 13:41:18

**US3082221**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:30:39
User entered '18'	(b) (4), (b) (6)	17 Mar 2021 13:41:18



**US3082221**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'breaths/min'	System	17 Mar 2021 13:41:18

**US3082221**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:30:39
User entered '127'	(b) (4), (b) (6)	17 Mar 2021 13:41:18

**US3082221**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'mmHg'	System	17 Mar 2021 13:41:18

**US3082221**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:30:39
User entered '81'	(b) (4), (b) (6)	17 Mar 2021 13:41:18

**US3082221**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered 'mmHg'	System	17 Mar 2021 13:41:18

**US3082221**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27

**US3082221**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:46**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27

**US3082221**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:57:46**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:30:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 13:41:37



**US3082221**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:57:46**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:30:58
User entered '17 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 13:41:37

**US3082221**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:31:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 13:41:51

**US3082221**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:31:15
User entered '17 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 13:41:51

**US3082221**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:31:15
User entered '09:12'	(b) (4), (b) (6)	17 Mar 2021 13:41:51

**US3082221**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:20:27
User entered '17 Mar 2021 09:12'	System	17 Mar 2021 13:41:51

**US3082221**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 21:57:46**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:36:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:32
User entered 'Yes (Y)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:16:53

**US3082221**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:57:46**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 16:09:55
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:18:38
User entered		
'USA-US114-2021-mRNA-1273-P301000003'	System	19 Jan 2021 23:18:09
User entered 'New'	(b) (4), (b) (6)	19 Jan 2021 23:18:09

US3082221

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:57:46

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 16:09:55
User closed query 'Per CDM: As per CCG, confirmed Covid-19 diagnosis has to be recorded with AE term Covid-19. Kindly review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:51:09
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	18 Jan 2021 13:46:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	18 Jan 2021 13:46:04
Data point term sent to Coder	System	18 Jan 2021 13:45:24
Query 'Per CDM: As per CCG, confirmed Covid-19 diagnosis has to be recorded with AE term Covid-19. Kindly review and update accordingly. Thank you.' answered with 'updated' (Site from DM).	Morgan Mathis (b) (4)	18 Jan 2021 13:44:41
Coding entries removed.	(b) (4)	
	Morgan Mathis (b) (4)	18 Jan 2021 13:44:33
User entered 'COVID-19' reason for change: Data Entry Error	(b) (4)	
	Morgan Mathis (b) (4)	18 Jan 2021 13:44:33
User opened query 'Per CDM: As per CCG, confirmed Covid-19 diagnosis has to be recorded with AE term Covid-19. Kindly review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 05:40:17
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)	15 Jan 2021 15:19:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	15 Jan 2021 15:19:53
Data point term sent to Coder	System	15 Jan 2021 15:18:49
User entered 'symptomatic covid-19'	Morgan Mathis (b) (4)	15 Jan 2021 15:18:26
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered 'Yes (Y)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:18:26

**US3082221**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:18:26

**US3082221**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered 'Yes (Y)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:18:26

US3082221

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:57:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User closed query 'PV Query: Please confirm the event onset date. Per the symptom log, Day 1 was 01 Jan 2021.Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol, if applicable.' (Site from Safety). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:59:58
Query 'PV Query: Please confirm the event onset date. Per the symptom log, Day 1 was 01 Jan 2021.Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol, if applicable.' answered with 'The subject was unblinded and given 1 dose of mRNA on 08Jan2021' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered '1 Jan 2021' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	27 Jan 2021 13:50:45
User opened query 'PV Query: Please confirm the event onset date. Per the symptom log, Day 1 was 01 Jan 2021.Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol, if applicable.' (Site from Safety). User entered '8 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 18:54:46
	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:18:26

US3082221

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:57:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4)	28 Jan 2021 16:09:55
	(b) (4), (b) (6)	
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	27 Jan 2021 13:51:00
User entered empty; reason for change Data Entry Error	Ayssa Valente (b) (4)	27 Jan 2021 13:51:00
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	27 Jan 2021 13:49:26
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Jan 2021 15:19:33
User entered '11:53' reason for change: Data Entry Error	Morgan Mathis (b) (4)	15 Jan 2021 15:19:33
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	15 Jan 2021 15:18:26
User entered empty.	Morgan Mathis (b) (4)	15 Jan 2021 15:18:26
	(b) (4)	

**US3082221**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:57:46**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 13:51:00
User entered '1 Jan 2021 11:53'	System	27 Jan 2021 13:49:26
User entered '8 Jan 2021 11:53'	System	15 Jan 2021 15:19:33
User entered empty.	System	15 Jan 2021 15:18:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:57:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:55
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	27 Jan 2021 13:51:00
User entered 'No (N)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	27 Jan 2021 13:51:00
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	27 Jan 2021 13:49:11
User entered 'Yes (Y)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:18:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:57:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:24:37
User closed query 'PV Query: End date was reported as 21 Jan 2021 but subject was still experiencing symptoms that day. Please confirm if end date should be 22 Jan 2021 instead as that is the first day all symptoms resolved.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 17:18:09
Query 'PV Query: End date was reported as 21 Jan 2021 but subject was still experiencing symptoms that day. Please confirm if end date should be 22 Jan 2021 instead as that is the first day all symptoms resolved.' answered with 'Updated to the correct end date' (Site from Safety).	Ayssa Valente (b) (4) (b) (4)	23 Feb 2021 13:16:33
DataPoint Un-verified.	Ayssa Valente (b) (4) (b) (4)	23 Feb 2021 13:16:17
Signature has been broken.	Ayssa Valente (b) (4) (b) (4)	23 Feb 2021 13:16:17
User entered '22 Jan 2021' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	23 Feb 2021 13:16:17
User opened query 'PV Query: End date was reported as 21 Jan 2021 but subject was still experiencing symptoms that day. Please confirm if end date should be 22 Jan 2021 instead as that is the first day all symptoms resolved.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 12:57:15
User signature succeeded.	Barton Williams (b) (4) (b) (4)	19 Feb 2021 18:53:24
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)	02 Feb 2021 21:00:08
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered '21 Jan 2021' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	27 Jan 2021 13:57:37
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 with end date' (Site from Safety).	Ayssa Valente (b) (4) (b) (4)	27 Jan 2021 13:51:12
User entered '19 Jan 2021' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	27 Jan 2021 13:49:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:57:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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). User entered empty.	(b) (4), (b) (6)	26 Jan 2021 18:58:41
	Morgan Mathis (b) (4)	15 Jan 2021 15:18:26
	(b) (4)	

**US3082221**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:57:46**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:18:26

**US3082221**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:57:46**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Jan 2021 15:18:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:57:46

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:18:26

**US3082221**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered 'No (N)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:18:26

**US3082221**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered '0'	Morgan Mathis (b) (4)	15 Jan 2021 15:18:26
	(b) (4)	

**US3082221**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered '0'	Morgan Mathis (b) (4)	15 Jan 2021 15:18:26
	(b) (4)	

**US3082221**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered '0'	Morgan Mathis (b) (4)	15 Jan 2021 15:18:26
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:57:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:18:26

US3082221

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:57:46

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:18:26

**US3082221**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:18:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:57:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:18:26

**US3082221**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered '0'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:18:26

**US3082221**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered '0'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:18:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:57:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered '0'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:18:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:57:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered 'Not Related (NOT RELATED)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:18:26



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:57:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered 'Not Related (NOT RELATED)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:18:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:57:46

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 15:24:37
User closed query 'PV Query: Thank you for confirming subject was unblinded and received first dose on 08 Jan 2021. However, Action Taken is in regard to the two doses of placebo taken prior to event onset. Therefore, since the subject received both doses of placebo prior to the onset of the event, please consider updating the action taken to not applicable. If not, please clarify.' (Site from Safety). Query 'PV Query: Thank you for confirming subject was unblinded and received first dose on 08 Jan 2021. However, Action Taken is in regard to the two doses of placebo taken prior to event onset. Therefore, since the subject received both doses of placebo prior to the onset of the event, please consider updating the action taken to not applicable. If not, please clarify.' answered with 'Action taken updated to not applicable' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 17:18:13
DataPoint Un-verified.	Ayssa Valente (b) (4)	23 Feb 2021 13:18:16
	(b) (4)	
Signature has been broken.	Ayssa Valente (b) (4)	23 Feb 2021 13:17:50
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Ayssa Valente (b) (4)	23 Feb 2021 13:17:50
User opened query 'PV Query: Thank you for confirming subject was unblinded and received first dose on 08 Jan 2021. However, Action Taken is in regard to the two doses of placebo taken prior to event onset. Therefore, since the subject received both doses of placebo prior to the onset of the event, please consider updating the action taken to not applicable. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 12:55:17
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
	(b) (4)	
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 21:00:23
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:09:55

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EAB) (1725)

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US3082221

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:57:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' answered with 'Subject was unblinded on 08Jan2021 and received 1 dose of mRNA' (Site from Safety).	Ayssa Valente (b) (4)	27 Jan 2021 13:51:45
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 18:55:50
User entered 'None (NONE)'	Morgan Mathis (b) (4)	15 Jan 2021 15:18:26

US3082221

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:57:46

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:24:37
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Un-verified.	(b) (4) Ayssa Valente (b) (4)	03 Feb 2021 15:01:14
User entered '0' reason for change: Data Entry Error	(b) (4) Ayssa Valente (b) (4)	03 Feb 2021 15:01:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:55
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Jan 2021 15:19:33
User entered '1' reason for change: Data Entry Error	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:19:33
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Jan 2021 15:18:26
User entered '0'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:18:26

US3082221

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:57:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:24:37
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Un-verified.	Ayssa Valente (b) (4)	03 Feb 2021 15:01:14
User entered '1' reason for change: Data Entry Error	Ayssa Valente (b) (4)	03 Feb 2021 15:01:14
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered '0'	Morgan Mathis (b) (4)	15 Jan 2021 15:18:26

**US3082221**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered '0'	Morgan Mathis (b) (4)	15 Jan 2021 15:18:26
	(b) (4)	

US3082221

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:57:46

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:00:35
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:09:55
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	Ayssa Valente (b) (4) (b) (4)	27 Jan 2021 13:51:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Ayssa Valente (b) (4) (b) (4)	27 Jan 2021 13:49:11
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 18:55:28
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:18:26

US3082221

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:57:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User closed query 'PV Query: Please complete symptom log beginning on Day 1, 01 Jan 2021, if available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:00:38
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:09:55
Query 'PV Query: Please complete symptom log beginning on Day 1, 01 Jan 2021, if available.' answered with 'updated with correct start date' (Site from Safety).	Ayssa Valente (b) (4) (b) (4)	27 Jan 2021 13:53:09
User opened query 'PV Query: Please complete symptom log beginning on Day 1, 01 Jan 2021, if available.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 18:55:01
User entered empty.	Morgan Mathis (b) (4) (b) (4)	15 Jan 2021 15:18:26



US3082221

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:57:46

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: It was confirmed that symptom log was updated with correct start date. However, it still shows as 01 Jan 2021 without any symptoms noted. Please update symptom log with symptoms accordingly. If symptoms are not available, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 17:18:16
Query 'PV Query: It was confirmed that symptom log was updated with correct start date. However, it still shows as 01 Jan 2021 without any symptoms noted. Please update symptom log with symptoms accordingly. If symptoms are not available, please state so.' answered with 'Symptoms for 01Jan2021-13 Jan2021 are unknown.' (Site from Safety).	Ayssa Valente (b) (4)	23 Feb 2021 13:20:14
User opened query 'PV Query: It was confirmed that symptom log was updated with correct start date. However, it still shows as 01 Jan 2021 without any symptoms noted. Please update symptom log with symptoms accordingly. If symptoms are not available, please state so.' (Site from Safety).	(b) (4)	23 Feb 2021 12:57:00
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:09:55
User entered empty.	Morgan Mathis (b) (4)	15 Jan 2021 15:18:26

**US3082221**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Jan 2021 15:18:26

**US3082221**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Jan 2021 15:18:26

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:57:46

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:36:48
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:12:45
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:32:17

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:57:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 13:34:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 13:34:47
Data point term sent to Coder	System	10 Sep 2020 13:33:43
User entered 'Magnesium'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:32:59

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:57:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:32:59

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'Supplement'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:32:59

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered '400'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:32:59



US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:57:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'mg (mg)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:32:59

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:57:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:32:59

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:57:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'other (OTHER)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:32:59

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:57:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'twice weekly'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:32:59

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'Oral (ORAL)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:32:59

US3082221

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:46**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:32:59

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:57:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'UN UNK 2019'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:32:59

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:57:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:32:59



**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:32:59

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:57:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:32:59

US3082221

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:32:59

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 13:32:59

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 13:32:59

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 13:32:59

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:57:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:44:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 19:44:48
Data point term sent to Coder	System	30 Sep 2020 17:18:48
Coding entries removed.	(b) (4), (b) (6)	30 Sep 2020 17:18:44
User entered 'ZYRTEC (CETIRIZINE AND HYDROCHLORIDE)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 17:18:44
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 13:35:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 13:35:49
Data point term sent to Coder	System	10 Sep 2020 13:34:47
User entered 'Zyrtec'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:33:56

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:57:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:33:56



US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:57:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'Allergic Rhinitis'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:33:56

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:57:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 17:13:07
User closed query 'Per DM CLR: Please review recorded dose as this is not the usual dose for this medication. Please review and update the dose as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 11:47:09
Query 'Per DM CLR: Please review recorded dose as this is not the usual dose for this medication. Please review and update the dose as appropriate. Otherwise, clarify. ' answered with 'Updated dosage' (Site from DM).	Alice Cipollini (b) (4)	08 Oct 2020 14:54:13
User entered '10' reason for change: Data Entry Error	(b) (4)	08 Oct 2020 14:54:05
User opened query 'Per DM CLR: Please review recorded dose as this is not the usual dose for this medication. Please review and update the dose as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:01:43
User entered '21'	Erin Harrelson (b) (4)	10 Sep 2020 13:33:56
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:57:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'mg (mg)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:33:56

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:57:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:33:56

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:57:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'as needed (PRN)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:33:56

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:57:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:33:56

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:57:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'Oral (ORAL)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:33:56

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:57:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:33:56



**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'UN UNK 2018'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:33:56

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:57:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:33:56

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:33:56

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:57:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:33:56

US3082221

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	10 Sep 2020 13:33:56

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 13:33:56

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 13:33:56

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 13:33:56



US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:57:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:35
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
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)	03 Nov 2020 14:45:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 14:45:20
Data point term sent to Coder	System	03 Nov 2020 14:45:03
User entered 'INFLUENZA VACCINE'	Erin Harrelson (b) (4) (b) (4)	03 Nov 2020 14:44:56

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:46**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:35
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'Yes (Y)'	Erin Harrelson (b) (4) (b) (4)	03 Nov 2020 14:44:56

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:46**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:35
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'INFLUENZA PROPHYLAXIS'	Erin Harrelson (b) (4) (b) (4)	03 Nov 2020 14:44:56

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:46**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:35
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered '0.5'	Erin Harrelson (b) (4) (b) (4)	03 Nov 2020 14:44:56

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:57:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:35
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'mL (mL)'	Erin Harrelson (b) (4) (b) (4)	03 Nov 2020 14:44:56

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:57:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:35
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	03 Nov 2020 14:44:56

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:57:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:35
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'once (ONCE)'	Erin Harrelson (b) (4) (b) (4)	03 Nov 2020 14:44:56

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:57:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:35
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	03 Nov 2020 14:44:56



US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:57:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:35
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'Intramuscular (INTRAMUSCULAR)'	Erin Harrelson (b) (4) (b) (4)	03 Nov 2020 14:44:56

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:57:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:35
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered empty.	Erin Harrelson (b) (4) (b) (4)	03 Nov 2020 14:44:56

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:57:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:35
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered '30 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	03 Nov 2020 14:44:56

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:35
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered '0'	Erin Harrelson (b) (4) (b) (4)	03 Nov 2020 14:44:56

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:46**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:35
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	03 Nov 2020 14:44:56

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:46**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:35
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered '30 Oct 2020'	Erin Harrelson (b) (4) (b) (4)	03 Nov 2020 14:44:56

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:57:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:35
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:13:07
User entered 'No (N)'	Erin Harrelson (b) (4) (b) (4)	03 Nov 2020 14:44:56

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:46**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:35
User entered empty.	System	03 Nov 2020 14:44:56



**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:46**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:35
User entered empty.	System	03 Nov 2020 14:44:56

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:46**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:35
User entered empty.	System	03 Nov 2020 14:44:56

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:57:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:38
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:12:23
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 15:13:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 15:13:05
Data point term sent to Coder	System	18 Jan 2021 15:06:57
User entered 'ibuprofen'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:06:23

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:46**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:38
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:12:23
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:06:23

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:57:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:38
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
User closed query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 20:54:49
Query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'Updated AE to reflect CM' (Site from DM).	Ayssa Valente (b) (4) (b) (4)	03 Feb 2021 15:01:32
User opened query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 09:16:14
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:12:23
User entered 'headache r/t covid-19'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:06:23

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:46**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:38
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:12:23
User entered '800'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:06:23

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:46**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:38
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:12:23
User entered 'mg (mg)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:06:23

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:57:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:38
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:12:23
User entered empty.	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:06:23



US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:57:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:38
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:12:23
User entered 'once (ONCE)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:06:23

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:57:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:38
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:12:23
User entered empty.	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:06:23

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:46**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:38
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:12:23
User entered 'Oral (ORAL)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:06:23

US3082221

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:46**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:38
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:12:23
User entered empty.	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:06:23

US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:57:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:38
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:12:23
User entered '15 Jan 2021'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:06:23

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:38
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:12:23
User entered '0'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:06:23

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:46**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:38
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:12:23
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:06:23

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:46**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:38
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:12:23
User entered '15 Jan 2021'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:06:23



US3082221

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:57:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:38
User signature succeeded.	Barton Williams (b) (4)	19 Feb 2021 18:53:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:12:23
User entered 'No (N)'	Ayssa Valente (b) (4) (b) (4)	18 Jan 2021 15:06:23

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:46**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:38
User entered empty.	System	18 Jan 2021 15:06:23

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:46**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:38
User entered empty.	System	18 Jan 2021 15:06:23

**US3082221**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:46**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:43:38
User entered empty.	System	18 Jan 2021 15:06:23

US3082221

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 21:57:46

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:25:01
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:41
User entered 'No (N)'	Ayssa Valente (b) (4)	03 Mar 2021 15:55:01

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:34:51
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 12:34:47
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'USA-US114-2021-MRNA-1273-P301000003'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09



**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'Barton'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'Williams'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered '3806 Peachtree Ave.'	System	19 Jan 2021 23:18:09



**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'Wilmington'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'NC'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered '28403'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:02:13
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:09:20
User entered 'US'	System	19 Jan 2021 23:19:24

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Mar 2021 13:34:23
User entered '2'	System	02 Feb 2021 21:01:51
User entered '1'	System	19 Jan 2021 23:19:24

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:34:51
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 12:34:47
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'USA-US114-2021-MRNA-1273-P301000003'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09



**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'Barton'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'Williams'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered '3806 Peachtree Ave.'	System	19 Jan 2021 23:18:09



**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'Wilmington'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'NC'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered '28403'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:02:13
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:09:20
User entered 'US'	System	19 Jan 2021 23:19:24

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Mar 2021 13:34:23
User entered '2'	System	02 Feb 2021 21:01:51
User entered '1'	System	19 Jan 2021 23:19:24

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 11 Aug 2021 21:57:46**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
User entered '19/Jan/2021 23:19'	System	19 Jan 2021 23:19:24

US3082221

Folder: SAE USA-US114-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:57:46

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:02:13
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:09:20
User entered 'I'	(b) (4), (b) (6)	19 Jan 2021 23:19:24

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:34:51
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 12:34:47
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'USA-US114-2021-MRNA-1273-P301000003'	System	19 Jan 2021 23:18:09



**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'Barton'	System	19 Jan 2021 23:18:09



**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'Williams'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered '3806 Peachtree Ave.'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'Wilmington'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'NC'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered '28403'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:02:13
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:09:20
User entered 'US'	System	19 Jan 2021 23:19:24

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Mar 2021 13:34:23
User entered '2'	System	02 Feb 2021 21:01:51
User entered '1'	System	19 Jan 2021 23:19:24

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 11 Aug 2021 21:57:46**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:24:06
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
User entered '02/Feb/2021 16:01'	(b) (4) System	02 Feb 2021 21:01:51



US3082221

Folder: SAE USA-US114-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:57:46

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:24:06
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:02:13
User entered 'I'	(b) (4), (b) (6)	02 Feb 2021 21:01:51

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:34:51
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 12:34:47
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'USA-US114-2021-MRNA-1273-P301000003'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09



**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'No (N)'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'Barton'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'Williams'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered '3806 Peachtree Ave.'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'Wilmington'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered 'NC'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:09:20
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 23:19:16
User entered '28403'	System	19 Jan 2021 23:18:09

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	05 Mar 2021 16:33:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 21:02:13
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:09:20
User entered 'US'	System	19 Jan 2021 23:19:24



**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:46**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Mar 2021 13:34:23
User entered '2'	System	02 Feb 2021 21:01:51
User entered '1'	System	19 Jan 2021 23:19:24

**US3082221**

**Folder: SAE USA-US114-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 11 Aug 2021 21:57:46**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:24:06
User entered '30/Mar/2021 06:34'	System	30 Mar 2021 13:34:23

US3082221

Folder: SAE USA-US114-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:57:46

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Barton Williams (b) (4)	16 Apr 2021 12:31:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:24:06
User entered 'I'	(b) (4), (b) (6)	30 Mar 2021 13:34:23