

US3022233 (Prod: Meridian Clinical Research-Savannah)

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:57:09

All time stamps listed in this document are displayed in GMT

US3022233

Form: Participant Creation

Data signed: (b) (4) 24 Feb 2021 00:20:48

Generated On: 11 Aug 2021 21:57:09

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[Participant ID](#)

US3022233

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

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US3022233

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Date of Birth (MMM yyyy)	(b) (6) 1967
Age	53
Age Units	YEARS
Age (Derived)	53
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	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Date of Informed Consent ( <i>dd MMM yyyy</i> )	20 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 24 Feb 2021 00:21:14

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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) 24 Feb 2021 00:21:14

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Condition	ECZEMA
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 24 Feb 2021 00:21:14

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	17:12 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 17:12
Height (xxx.x)	167.6 cm
Weight (xxx.x)	76.6 kg
BMI (xxx.x)	27.26972 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:21:14

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 24 Feb 2021 00:21:14

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Date of assessment (dd MMM yyyy) 20 AUG 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

If Partner medically sterile or Other, specify \_\_\_\_\_  
If Surgically sterile, date of surgery (dd MMM yyyy) \_\_\_\_\_  
Date of surgery unknown False  
If Post-menopausal, date of last menstruation (dd MMM yyyy) \_\_\_\_\_  
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 20 AUG 2020

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: Screening

Form: Risk of Exposure

Data signed: (b) (4) 24 Feb 2021 00:21:14

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 24 Feb 2021 00:21:14

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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)	True
<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) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

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

What was the participant's randomization number? 106763

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) 24 Feb 2021 00:21:14

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	17:12 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 17:12
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	19:01 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 19:01
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

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) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

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) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 18:30 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 18:30

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) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 AUG 2020
Collection time (00:00-23:59)	17:22 (24 HR)
Collection date and time (derived)	20 AUG 2020 17:22

US3022233

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Collection date (dd MMM yyyy)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:32	20 AUG 2020 17:32
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

**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

20 AUG 2020 19:02

PC Open Date & Time

20 AUG 2020 18:50

PC Close Date & Time

20 AUG 2020 21:20

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

**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 97.6 °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	21 AUG 2020 08:07
PC Open Date & Time	20 AUG 2020 22:15
PC Close Date & Time	21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:09

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

22 AUG 2020 08:10

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:09

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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.

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Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

96.2 °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

23 AUG 2020 00:38

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PC Open Date & Time

22 AUG 2020 12:00

---

PC Close Date & Time

23 AUG 2020 11:59

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US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:09

**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

97.3 °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

24 AUG 2020 00:06

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59



US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:09

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.2 °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

24 AUG 2020 16:53

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PC Open Date & Time

24 AUG 2020 12:00

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PC Close Date & Time

25 AUG 2020 11:59

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US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:09

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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

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

25 AUG 2020 17:08

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:09

**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

97.4 °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

26 AUG 2020 15:59

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 19:02

PC Open Date & Time

20 AUG 2020 18:50

PC Close Date & Time

20 AUG 2020 21:20

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

**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

21 AUG 2020 08:08

PC Open Date & Time

20 AUG 2020 22:15

PC Close Date & Time

21 AUG 2020 11:59

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:09

**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

22 AUG 2020 08:10

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:09

**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

23 AUG 2020 00:39

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:09

**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

24 AUG 2020 00:06

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59



US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 16:53

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 17:09

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 16:00

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

**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 ☐

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 19:03
PC Open Date & Time	20 AUG 2020 18:50
PC Close Date & Time	20 AUG 2020 21:20

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

**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 ☐

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 08:08
PC Open Date & Time	20 AUG 2020 22:15
PC Close Date & Time	21 AUG 2020 11:59

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:09

**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 ☒



US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:09

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 08:11
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:09

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 ☒

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:09

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

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:09

**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 ☒

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EAB) (1725)

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US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:09

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 00:06
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 2857

EAB) (1725)

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:09

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 16:53
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 2857

EAB) (1725)



US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:09

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 17:09
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:09

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 ☒

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:09

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 16:01
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3022233

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:21:13

Generated On: 11 Aug 2021 21:57:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022233

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:21:13

Generated On: 11 Aug 2021 21:57:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022233

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:21:13

Generated On: 11 Aug 2021 21:57:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022233

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:21:13

Generated On: 11 Aug 2021 21:57:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022233

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:21:13

Generated On: 11 Aug 2021 21:57:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3022233

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:21:13

Generated On: 11 Aug 2021 21:57:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022233

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	15:52 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 15:52
Temperature (xxx.x)	36.9 C
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)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	17:08 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 17:08
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3022233

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3022233

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	24 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)	

US3022233

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

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) 24 SEP 2020

What was the treatment time? (00:00-23:59) 16:38 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 16:38

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

US3022233

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 SEP 2020

Collection time (00:00-23:59)

16:01 (24 HR)

Collection date and time (derived)

24 SEP 2020 16:01



US3022233

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:10	24 SEP 2020 16:10
Nasopharyngeal Swab 2	No		

US3022233

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

**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

98.0 °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

24 SEP 2020 17:11

PC Open Date & Time

24 SEP 2020 16:58

PC Close Date & Time

24 SEP 2020 19:28

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

**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

96.2 °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

25 SEP 2020 08:20

PC Open Date & Time

24 SEP 2020 20:23

PC Close Date & Time

25 SEP 2020 11:59

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 00:01

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:09

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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

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

26 SEP 2020 14:02

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:09

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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

28 SEP 2020 06:14

---

PC Open Date & Time

27 SEP 2020 12:00

---

PC Close Date & Time

28 SEP 2020 11:59

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US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:09

**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

97.6 °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

29 SEP 2020 09:01

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59



US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:09

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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

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

30 SEP 2020 09:35

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:09

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**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.

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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

30 SEP 2020 12:01

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 17:12

PC Open Date & Time

24 SEP 2020 16:58

PC Close Date & Time

24 SEP 2020 19:28

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

**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

25 SEP 2020 08:21

PC Open Date & Time

24 SEP 2020 20:23

PC Close Date & Time

25 SEP 2020 11:59

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:09

**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

26 SEP 2020 00:01

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:09

**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

26 SEP 2020 14:02

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:09

**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

28 SEP 2020 06:15

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:09

**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

29 SEP 2020 09:01

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59



US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:09

**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

30 SEP 2020 09:35

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:09

**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

30 SEP 2020 12:01

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

**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 ☐

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 17:12
PC Open Date & Time	24 SEP 2020 16:58
PC Close Date & Time	24 SEP 2020 19:28

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

**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 ☐

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 08:21
PC Open Date & Time	24 SEP 2020 20:23
PC Close Date & Time	25 SEP 2020 11:59

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:09

**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 ☒

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:09

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 00:02
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59



US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:09

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 ☒

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:09

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 14:02
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:09

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 06:15
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:09

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 ☒

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:09

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 09:02
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:09

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 ☒

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:09

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 09:36
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59



US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:09

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 12:01
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3022233

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:21:13

Generated On: 11 Aug 2021 21:57:09

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*

US3022233

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:21:13

Generated On: 11 Aug 2021 21:57:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022233

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:21:13

Generated On: 11 Aug 2021 21:57:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022233

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:21:13

Generated On: 11 Aug 2021 21:57:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022233

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:21:13

Generated On: 11 Aug 2021 21:57:09

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

US3022233

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:21:13

Generated On: 11 Aug 2021 21:57:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3022233

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

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

US3022233

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 NOV 2020
Time of assessment (00:00-23:59)	16:26 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 16:26
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022233

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 NOV 2020

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

US3022233

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 NOV 2020
Collection time (00:00-23:59)	16:34 (24 HR)
Collection date and time (derived)	16 NOV 2020 16:34

US3022233

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022233

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 OCT 2020 13:39:21

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3022233

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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

27 OCT 2020 07:16:24

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3022233

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>



**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3022233

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 05:34:20

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 04:46:20
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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

29 NOV 2020 14:07:04

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 08:15:51
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 12:26:07

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

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	21 DEC 2020 12:44:21
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 07:16:18

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59



US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 00:22:12

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

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 <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	09 JAN 2021 07:45:47
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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

18 JAN 2021 12:00:56

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 19:06:43

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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

02 FEB 2021 11:14:19

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 09:34:55

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 00:24:50

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 17:24:05

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59



US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	27 FEB 2021 04:47:59
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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

09 MAR 2021 13:44:42

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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

13 MAR 2021 08:23:04

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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

23 MAR 2021 21:45:36

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

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 <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"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

27 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 05:58:09

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

<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	12 APR 2021 19:00:05
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59



US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 APR 2021 12:01:00
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 20:20:53

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐ 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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

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"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59



US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐  
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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐ 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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐  
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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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°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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2021 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐  
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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	10 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2021 23:59



US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

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

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

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"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59



US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐ 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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2021 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

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

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

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

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

02 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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



US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐  
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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 NOV 2021 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐ 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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐ 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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

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

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

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

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

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

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[Patient Cloud Open Date & Time](#)

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18 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 DEC 2021 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐ 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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59



US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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°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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

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

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[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐ 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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59



US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

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"/>

**US3022233**

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

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**Generated On: 11 Aug 2021 21:57:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

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13 APR 2022 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐ 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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	16 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 APR 2022 23:59



US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

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"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

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"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐  
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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59



US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

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

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[Patient Cloud Open Date & Time](#)

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18 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUN 2022 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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25 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUN 2022 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

02 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐ 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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

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"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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20 JUL 2022 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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23 JUL 2022 00:01

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27 JUL 2022 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

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"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

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"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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10 AUG 2022 23:59



US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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17 AUG 2022 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐  
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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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20 AUG 2022 00:01

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24 AUG 2022 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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27 AUG 2022 00:01

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31 AUG 2022 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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°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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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07 SEP 2022 23:59



US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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°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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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14 SEP 2022 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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21 SEP 2022 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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28 SEP 2022 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

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 <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"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

01 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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[Patient Cloud Close Date & Time](#)

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12 OCT 2022 23:59

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US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**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°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 ☐

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	15 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2022 23:59

US3022233

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

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"/>

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	22 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2022 23:59

US3022233

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 21:57:09

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		09 MAR 2021 13:45:03

US3022233

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3022233

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022233

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:20:53

Generated On: 11 Aug 2021 21:57:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022233

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:20:53

Generated On: 11 Aug 2021 21:57:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022233

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:21:13

Generated On: 11 Aug 2021 21:57:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022233

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:21:13

Generated On: 11 Aug 2021 21:57:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022233

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3022233

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022233

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	VISIT4



US3022233

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 22:21:07

Generated On: 11 Aug 2021 21:57:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	09 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	14:23 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 14:23
Temperature ( <i>xxx.x</i> )	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	82 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022233

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 MAR 2021

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

US3022233

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 MAR 2021
Collection time (00:00-23:59)	14:14 (24 HR)
Collection date and time (derived)	09 MAR 2021 14:14

US3022233

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3022233**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

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*

**US3022233**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Date of Contact	09 OCT 2020
Time of Contact	09:00
Date and Time of Contact (derived)	09 OCT 2020 09:00
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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"/>



US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	02 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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 ☐

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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"/>

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	03 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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 ☐

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Symptom Day

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



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Form: Symptom Log (3)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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 09 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	05 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (5)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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 09 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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	06 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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 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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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (6)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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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Form: Symptom Log (6)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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	07 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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 ☐

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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 09 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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	08 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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 09 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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 09 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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	09 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	37.1 C
-------------	--------

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 09 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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 type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	99.9 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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EAB) (1725)

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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 type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

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

Temperature	99.1 F
-------------	--------

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

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

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

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

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Form: Symptom Log (10)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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 type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Symptom Day

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



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Form: Symptom Log (11)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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 type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Symptom Day

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

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Symptom Day

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



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Form: Symptom Log (13)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	95.8 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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Form: Symptom Log (13)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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"/>

PRODUCTION RELEASE (v12.003

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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 (14)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Symptom Day

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

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Form: Symptom Log (14)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input 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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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (15)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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"/>



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Form: Symptom Log (15)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	96.8 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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Form: Symptom Log (15)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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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EAB) (1725)

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Form: Symptom Log (16)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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 (17)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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"/>

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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"/>

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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 ☐

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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 09 Oct 2020

Form: Symptom Log (19)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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 09 Oct 2020

Form: Symptom Log (28)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 OCT 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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 ☐

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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 09 Oct 2020

Form: Symptom Log (29)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	22 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	97.5 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

	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"/>

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

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 ☐

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

Date of Visit 09 OCT 2020

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

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

Date of Test 09 OCT 2020

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

Other, specify \_\_\_\_\_

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

If yes, provide lab information below

Lab/ Institution Test Performed \_\_\_\_\_

CLIA Certified? Yes ☐  
No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Mar 2021 23:01:28

Generated On: 11 Aug 2021 21:57:09

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 21 OCT 2020

End Date 21 OCT 2020

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 \_\_\_\_\_

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Mar 2021 23:01:28

Generated On: 11 Aug 2021 21:57:09

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

**Ventilator Support:**

High-Flow Oxygen? Yes ☐  
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐  
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐  
No ☐

Start Date

End Date

ECMO? Yes ☐  
No ☐

Start Date

End Date

**Evidence of Shock:**

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

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐  
No ☐

Start Date

End Date

Acute Renal Dysfunction? Yes ☐  
No ☐

Start Date

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US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Mar 2021 23:01:28

Generated On: 11 Aug 2021 21:57:09

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

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 24 Feb 2021 00:20:50

Generated On: 11 Aug 2021 21:57:09

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---



US3022233

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 24 Feb 2021 00:20:51

Generated On: 11 Aug 2021 21:57:09

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	11 OCT 2020
Day 5	Yes	13 OCT 2020
Day 7	Yes	15 OCT 2020
Day 9	Yes	17 OCT 2020
Day 14	Yes	22 OCT 2020
Day 21	Yes	29 OCT 2020
Day 28	Yes	09 NOV 2020

US3022233

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:20:51

Generated On: 11 Aug 2021 21:57:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3022233

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Feb 2021 00:20:51

Generated On: 11 Aug 2021 21:57:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 OCT 2020
Time of assessment (00:00-23:59)	11:53 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 11:53
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022233

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:20:51

Generated On: 11 Aug 2021 21:57:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 OCT 2020

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

US3022233

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 24 Feb 2021 00:20:51

Generated On: 11 Aug 2021 21:57:09

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

09 OCT 2020

US3022233

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:20:49

Generated On: 11 Aug 2021 21:57:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3022233

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Feb 2021 00:20:49

Generated On: 11 Aug 2021 21:57:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 NOV 2020
Time of assessment (00:00-23:59)	15:38 (24 HR)
Vital Signs Date and Time (derived)	09 NOV 2020 15:38
Height (xxx.x)	167.6 cm
Weight (xxx.x)	78.4 kg
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022233

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:20:49

Generated On: 11 Aug 2021 21:57:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 NOV 2020

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



US3022233

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 24 Feb 2021 00:20:49

Generated On: 11 Aug 2021 21:57:09

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

09 NOV 2020

US3022233

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

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:20:52

Generated On: 11 Aug 2021 21:57:09

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

Visit date (dd MMM yyyy)	26 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3022233

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 22:21:07

Generated On: 11 Aug 2021 21:57:09

Date of updated informed consent ( <i>dd MMM yyyy</i> )	26 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	26 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3022233

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Feb 2021 00:20:52

Generated On: 11 Aug 2021 21:57:09

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3022233

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 00:20:52

Generated On: 11 Aug 2021 21:57:09

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	16:04 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 16:04
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3022233

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 00:20:52

Generated On: 11 Aug 2021 21:57:09

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	17:00 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 17:00
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3022233

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

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:20:52

Generated On: 11 Aug 2021 21:57:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 JAN 2021

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

US3022233

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

Form: Pregnancy Test

Data signed: (b) (4) 24 Feb 2021 00:20:52

Generated On: 11 Aug 2021 21:57:09

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (dd MMM yyyy)	26 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)	



US3022233

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

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 00:20:52

Generated On: 11 Aug 2021 21:57:09

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 JAN 2021

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

Treatment Date and Time (derived) 26 JAN 2021 16:27

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

What was the frequency of the study treatment dosing? ONCE

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

US3022233

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 00:20:52

Generated On: 11 Aug 2021 21:57:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 JAN 2021

Collection time (00:00-23:59)

15:42 (24 HR)

Collection date and time (derived)

26 JAN 2021 15:42

US3022233

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Feb 2021 00:20:51

Generated On: 11 Aug 2021 21:57:09

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

Collection date (dd MMM yyyy)	26 JAN 2021
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Collection time (00:00 - 23:59)	15:51
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Collection Date and Time (derived)	26 JAN 2021 15:51
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US3022233

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

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:20:52

Generated On: 11 Aug 2021 21:57:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022233

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022233

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:21:14

Generated On: 11 Aug 2021 21:57:09

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3022233

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	OLD29

US3022233

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

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)	09 MAR 2021
Time of assessment (00:00-23:59)	14:23 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 14:23
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG



US3022233

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

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)	09 MAR 2021
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 15:20
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3022233

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 MAR 2021

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

US3022233

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 09 MAR 2021

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

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

US3022233

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

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) 09 MAR 2021

What was the treatment time? (00:00-23:59) 14:50 (24 HR)

Treatment Date and Time (derived) 09 MAR 2021 14:50

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

US3022233

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022233

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022233

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3022233**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

Was this visit performed? Yes ☐  
No ☐

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

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

Folder OID \_\_\_\_\_



US3022233

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

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

US3022233

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:09

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.*

**US3022233**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:09**

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

US3022233

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 24 Feb 2021 00:20:49

Generated On: 11 Aug 2021 21:57:09

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3022233

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 25 Mar 2021 23:08:12

Generated On: 11 Aug 2021 21:57:09

AEID	USA-US051-2020-MRNA-1273-P30 1000008
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)	02 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	21 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 25 Mar 2021 23:08:12

Generated On: 11 Aug 2021 21:57:09

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	NONE
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)	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 25 Mar 2021 23:08:12

Generated On: 11 Aug 2021 21:57:09

AEID

Adverse event

GUM INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

31 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

24 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 25 Mar 2021 23:08:12

Generated On: 11 Aug 2021 21:57:09

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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)	_____



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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 25 Mar 2021 23:08:12

Generated On: 11 Aug 2021 21:57:09

AEID

Adverse event

HERPES ZOSTER

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

20 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 25 Mar 2021 23:08:12

Generated On: 11 Aug 2021 21:57:09

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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)	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 25 Mar 2021 23:08:12

Generated On: 11 Aug 2021 21:57:09

AEID

Adverse event

POSTERIOR CERVICAL  
LYMPHADENOPATHY

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

20 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 25 Mar 2021 23:08:12

Generated On: 11 Aug 2021 21:57:09

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 24 Feb 2021 00:20:49

Generated On: 11 Aug 2021 21:57:09

---

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

Yes ☒

No ☐

---

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

---

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

Name of Medication ALEVE

Prophylaxis Yes ☐  
No ☒

Indication COVID-19

Dose per administration 375

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 (1)

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

	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)		02 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐  
No ☒

Indication GUM INFECTION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

	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)	31 JAN 2021	
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)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PREVENTION

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 (3)

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐  
No ☒

Indication GUM INFECTION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

	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)	31 JAN 2021	
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)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

Name of Medication VALACYCLOVIR

Prophylaxis Yes ☐  
No ☒

Indication HERPES ZOSTER

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

	Intramuscular	<input 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)	20 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	02 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

Name of Medication DICLOFENAC

Prophylaxis Yes ☐  
No ☒

Indication HERPES ZOSTER

Dose per administration 75

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 (6)

Data signed: (b) (4) 25 Mar 2021 23:08:13

Generated On: 11 Aug 2021 21:57:09

	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)	20 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	02 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3022233

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 13 Apr 2021 22:21:07

Generated On: 11 Aug 2021 21:57:09

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3022233

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:57:09

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:57:09

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 ☐

US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 24 Feb 2021 00:20:53

Generated On: 11 Aug 2021 21:57:09

SAEID	USA-US051-2020-MRNA-1273-P301000008
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Feb 2021 00:20:53

Generated On: 11 Aug 2021 21:57:09

SAEID	USA-US051-2020-MRNA-1273-P301000008
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	15/OCT/2020 13:07
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

US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Feb 2021 00:20:53

Generated On: 11 Aug 2021 21:57:09

SAEID	USA-US051-2020-MRNA-1273-P301000008
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	27/OCT/2020 17:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Feb 2021 00:20:53

Generated On: 11 Aug 2021 21:57:09

SAEID	USA-US051-2020-MRNA-1273-P301000008
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	03/NOV/2020 22:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 24 Feb 2021 00:20:53

Generated On: 11 Aug 2021 21:57:09

SAEID	USA-US051-2020-MRNA-1273-P301000008
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	04/NOV/2020 14:39
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

US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Data signed: (b) (4) 24 Feb 2021 00:20:53

Generated On: 11 Aug 2021 21:57:09

SAEID	USA-US051-2020-MRNA-1273-P301000008
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	10/NOV/2020 17:52
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form (6)

Data signed: (b) (4) 24 Feb 2021 00:20:53

Generated On: 11 Aug 2021 21:57:09

SAEID	USA-US051-2020-MRNA-1273-P301000008
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	21/NOV/2020 11:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3022233 (Prod: Meridian Clinical Research-Savannah)

**US3022233**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 21:57:09**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:52:12
User entered 'US3022233'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 21:14:49

**US3022233**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 13:07:38
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '20 AUG 2020'	RWS_ENDPOINT	20 Aug 2020 21:14:50
	ENDPOINT (b) (4)	

US3022233

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:57:09

[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 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Clinic (Clinic)'	Stella Yoon (b) (4)	21 Aug 2020 13:07:38
	(b) (4)	



**US3022233**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered 'SCRN'	(b) (4), (b) (6) System	21 Aug 2020 13:07:38

US3022233

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:57:09

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered (b) (6) 1967'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 21:14:51

**US3022233**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:09**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '53'	Stella Yoon (b) (4)	21 Aug 2020 13:07:51
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:09**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered 'YEARS'	(b) (4), (b) (6) System	21 Aug 2020 13:07:51

**US3022233**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:09**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered '53'	(b) (4), (b) (6) System	20 Aug 2020 22:50:28

**US3022233**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:09**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Female (F)'	Stella Yoon (b) (4)	21 Aug 2020 13:07:51
	(b) (4)	

US3022233

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:57:09

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Stella Yoon (b) (4)	21 Aug 2020 13:07:51
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:09**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 13:07:51
	(b) (4)	



US3022233

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:57:09

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'I'	Stella Yoon (b) (4)	21 Aug 2020 13:07:51
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:09**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 13:07:51
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:09**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 13:07:51
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:09**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 13:07:51
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:09**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 13:07:51
	(b) (4)	

US3022233

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:57:09

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 13:07:51
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:09**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 13:07:51
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:57:09**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 13:07:51
	(b) (4)	



US3022233

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:57:09

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '20 Aug 2020'	Shanice Bennett (b) (4)	20 Aug 2020 22:50:28
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered 'Aug 2020'	(b) (4), (b) (6) System	20 Aug 2020 22:50:28

**US3022233**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered '2020'	(b) (4), (b) (6) System	20 Aug 2020 22:50:28

**US3022233**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:57:09**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Amendment 2 (2)'	Shanice Bennett (b) (4)	20 Aug 2020 22:50:28
	(b) (4)	

US3022233

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	20 Aug 2020 22:50:28
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Aug 2020 22:50:28
	(b) (4)	

US3022233

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:57:09

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Aug 2020 22:50:28
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:57:09**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	20 Aug 2020 22:50:28
	(b) (4)	



US3022233

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:57:09

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	RWS_ENDPOINT	20 Aug 2020 21:14:50
	ENDPOINT (b) (4)	

**US3022233**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:57:09**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered 'I'	(b) (4), (b) (6) System	20 Aug 2020 22:50:35

US3022233

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	20 Aug 2020 22:50:35
	(b) (4)	

US3022233

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 21:57:09

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 13:07:58
	(b) (4)	

US3022233

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:57:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 13:09:18
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 13:09:18
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 13:08:41
User entered 'eczema'	Stella Yoon (b) (4)	21 Aug 2020 13:08:21
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'un UNK 2012'	Stella Yoon (b) (4)	21 Aug 2020 13:08:21
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 13:08:21
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 13:08:21
	(b) (4)	



**US3022233**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 13:08:21
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 13:08:21
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered 'Jan 2012'	(b) (4), (b) (6) System	21 Aug 2020 13:08:21

**US3022233**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered '2012'	(b) (4), (b) (6) System	21 Aug 2020 13:08:21

**US3022233**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 13:08:21

**US3022233**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 13:08:21

US3022233

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:57:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 04:53:50
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 04:53:50
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 13:08:41
User entered 'allergy monocycline'	Stella Yoon (b) (4)	21 Aug 2020 13:08:35
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'un UNK 2010'	Stella Yoon (b) (4)	21 Aug 2020 13:08:35
	(b) (4)	



**US3022233**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 13:08:35
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 13:08:35
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 13:08:35
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 13:08:35
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered 'Jan 2010'	(b) (4), (b) (6) System	21 Aug 2020 13:08:35

**US3022233**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered '2010'	(b) (4), (b) (6) System	21 Aug 2020 13:08:35

**US3022233**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 13:08:35

**US3022233**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 13:08:35



US3022233

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:57:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User closed query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 17:20:00
Query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Stella Yoon (b) (4)	30 Sep 2020 18:42:49
	(b) (4)	
User opened query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 03:48:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 13:11:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 13:11:24
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 13:09:41
User entered 'bilateral tubal ligation'	Stella Yoon (b) (4)	21 Aug 2020 13:08:52
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'un UNK 2002'	Stella Yoon (b) (4)	21 Aug 2020 13:08:52
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:57:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 13:08:52
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:57:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Stella Yoon (b) (4)	21 Aug 2020 13:08:59
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 13:08:52
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'un UNK 2002' reason for change:	Stella Yoon (b) (4)	21 Aug 2020 13:08:59
Data Entry Error	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 13:08:52
	(b) (4)	

US3022233

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:57:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 13:08:52
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered 'Jan 2002'	(b) (4), (b) (6) System	21 Aug 2020 13:08:52

**US3022233**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered '2002'	(b) (4), (b) (6) System	21 Aug 2020 13:08:52



**US3022233**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User entered 'Jan 2002'	System	21 Aug 2020 13:08:59
User entered empty.	System	21 Aug 2020 13:08:52

**US3022233**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User entered '2002'	System	21 Aug 2020 13:08:59
User entered empty.	System	21 Aug 2020 13:08:52

US3022233

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 13:10:00
	(b) (4)	

US3022233

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '20 Aug 2020'	Stella Yoon (b) (4)	21 Aug 2020 13:10:00
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '17:12'	Stella Yoon (b) (4)	21 Aug 2020 13:10:00
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered '20 Aug 2020 17:12'	(b) (4), (b) (6) System	21 Aug 2020 13:10:00

US3022233

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '167.6' cm	Stella Yoon (b) (4)	21 Aug 2020 13:10:00
	(b) (4)	
DataPoint set to visible.	System	20 Aug 2020 22:50:35

US3022233

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '76.6' kg	Stella Yoon (b) (4)	21 Aug 2020 13:10:00
	(b) (4)	
DataPoint set to visible.	System	20 Aug 2020 22:50:35



US3022233

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
Amendment Manager: User entered '27.26972'	(b) (4), (b) (6)	
User entered '27.3'	System	17 Sep 2020 00:17:17
DataPoint set to visible.	System	21 Aug 2020 13:10:00
	System	20 Aug 2020 22:50:35

US3022233

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	21 Aug 2020 13:10:00
DataPoint set to visible.	System	20 Aug 2020 22:50:35

US3022233

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:21:14
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) (4), (b) (6)	10 Nov 2020 09:03:43
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 'UPDATED' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:37:04
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:36:53
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)	22 Oct 2020 11:05:10
User entered '36.5' C	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 13:10:00

US3022233

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:36:53
User entered 'Oral (Oral)'	Stella Yoon (b) (4)	21 Aug 2020 13:10:00
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 13:10:00
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	09 Nov 2020 22:36:53
change Data Entry Error		
User entered '98'	Stella Yoon (b) (4)	21 Aug 2020 13:10:00
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered 'bpm'	(b) (4), (b) (6) System	21 Aug 2020 13:10:00

US3022233

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	09 Nov 2020 22:36:53
change Data Entry Error		
User entered '12'	Stella Yoon (b) (4)	21 Aug 2020 13:10:00
	(b) (4)	



US3022233

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered 'breaths/min'	(b) (4), (b) (6) System	21 Aug 2020 13:10:00

US3022233

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	09 Nov 2020 22:36:53
change Data Entry Error		
User entered '112'	Stella Yoon (b) (4)	21 Aug 2020 13:10:00
	(b) (4)	

US3022233

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 13:10:00

US3022233

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	09 Nov 2020 22:36:53
change Data Entry Error		
User entered '66'	Stella Yoon (b) (4)	21 Aug 2020 13:10:00
	(b) (4)	

US3022233

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 13:10:00

US3022233

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:35:59

**US3022233**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:35:59

US3022233

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 13:10:08
	(b) (4)	



US3022233

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:09

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '20 Aug 2020'	Stella Yoon (b) (4)	21 Aug 2020 13:10:08
	(b) (4)	

US3022233

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:57:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '20 Aug 2020'	Stella Yoon (b) (4)	21 Aug 2020 13:10:23
	(b) (4)	

US3022233

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:40:12
User entered 'No (N)' reason for change: Data Entry Error	Stella Yoon (b) (4)	30 Sep 2020 18:42:35
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 13:10:23
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:57:09

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:40:12
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	Stella Yoon (b) (4)	30 Sep 2020 18:42:35
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 13:10:23
	(b) (4)	

US3022233

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:57:09

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 13:10:23
	(b) (4)	

US3022233

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:40:12
User entered 'un UNK 2002' reason for change: Data Entry Error	Stella Yoon (b) (4)	30 Sep 2020 18:42:35
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 13:10:23
	(b) (4)	

US3022233

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:57:09

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 13:10:23
	(b) (4)	

US3022233

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 13:10:23
	(b) (4)	



US3022233

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:57:09

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 13:10:23
	(b) (4)	

US3022233

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:57:09

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User closed query 'Per CDM: "Is the participant of Childbearing potential?" is marked as "No"; however, pregnancy test data is recorded. Please review, reconcile and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 09:10:24
Query 'Per CDM: "Is the participant of Childbearing potential?" is marked as "No"; however, pregnancy test data is recorded. Please review, reconcile and update as appropriate, else clarify. Thank you.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:40:25
User opened query 'Per CDM: "Is the participant of Childbearing potential?" is marked as "No"; however, pregnancy test data is recorded. Please review, reconcile and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:03:29
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 13:11:02
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '20 Aug 2020'	Stella Yoon (b) (4)	21 Aug 2020 13:11:02
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Urine (URINE)'	Stella Yoon (b) (4)	21 Aug 2020 13:11:02
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Stella Yoon (b) (4)	21 Aug 2020 13:11:02
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 13:11:02
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 13:11:02
	(b) (4)	

**US3022233**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 13:11:02
	(b) (4)	



**US3022233**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 13:11:02

US3022233

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:09

[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 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 13:10:48
	(b) (4)	

US3022233

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:09

**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 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 13:10:48
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:09

**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 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 13:10:48
	(b) (4)	

US3022233

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:09

**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 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 13:10:48
	(b) (4)	

US3022233

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:09

[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 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 13:10:48
	(b) (4)	

US3022233

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:09

[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 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 13:10:48
	(b) (4)	

US3022233

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:09

**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 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 13:10:48
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

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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 13:35:59
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4)	21 Aug 2020 13:10:48

US3022233

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:09

[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 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 13:10:48
	(b) (4)	

US3022233

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:09

**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 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 13:10:48
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:09

**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 13:35:59
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 13:10:48
	(b) (4)	

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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 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 13:10:48
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:09

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 13:10:48
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 13:10:48
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 13:10:48
	(b) (4)	



US3022233

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:09

**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 13:35:59
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	21 Aug 2020 13:10:48

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:09

[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 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 13:10:48
	(b) (4)	

US3022233

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:09

**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 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'I'	Stella Yoon (b) (4)	21 Aug 2020 13:10:48
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 13:10:48
	(b) (4)	

US3022233

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:09

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 13:10:48
	(b) (4)	

US3022233

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:57:09

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 13:10:48
	(b) (4)	

**US3022233**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	21 Aug 2020 13:11:13

**US3022233**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User entered '20 Aug 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	21 Aug 2020 13:11:13



US3022233

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User entered 'Clinic (Clinic)'	(b) (4) Stella Yoon (b) (4) (b) (4)	21 Aug 2020 13:11:13

**US3022233**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'VISIT1'	(b) (4), (b) (6) System	21 Aug 2020 13:11:13

US3022233

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '20 AUG 2020'	RWS_ENDPOINT	20 Aug 2020 21:49:11
	ENDPOINT (b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 06:04:13
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 06:04:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 21:49:11
User entered '106763' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 21:49:11

US3022233

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT	20 Aug 2020 21:49:11
	ENDPOINT (b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:57:09

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)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 13:11:27
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:57:09

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)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 13:11:27
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 13:11:27
	(b) (4)	



**US3022233**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 13:11:27
	(b) (4)	

**US3022233**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:57:09**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 13:11:27
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:57:09

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:12:23
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:28:00
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 22:27:51
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 17:40:25
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:37:39
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:52:57

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:57:09

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 09:04:06
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:41:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:29:33
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:42:30
User entered '167.6' cm	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 13:12:47

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:57:09

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:29:33
User entered '76.6' kg	Stella Yoon (b) (4)	21 Aug 2020 13:12:47

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:57:09

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 09:04:06
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:41:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:29:33
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:42:30
User entered '167.6' cm	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 13:12:47

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:57:09

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	09 Nov 2020 22:29:33
change Data Entry Error		
User entered '76.6' kg	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	21 Aug 2020 13:12:47



US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '20 Aug 2020'	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '17:12'	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	

**US3022233**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered '20 Aug 2020 17:12'	(b) (4), (b) (6) System	21 Aug 2020 13:12:47

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '36.5' C	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Oral (Oral)'	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '98'	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	



US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'bpm'	(b) (4), (b) (6) System	21 Aug 2020 13:12:47

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '12'	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'breaths/min'	(b) (4), (b) (6) System	21 Aug 2020 13:12:47

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '112'	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 13:12:47

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '66'	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 13:12:47

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:57:09

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 09:04:06
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:41:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:29:33
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:42:30
User entered '167.6' cm	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 13:12:47



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:57:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	09 Nov 2020 22:29:33
change Data Entry Error		
User entered '76.6' kg	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	21 Aug 2020 13:12:47

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '20 Aug 2020'	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '19:01'	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered '20 Aug 2020 19:01'	(b) (4), (b) (6) System	21 Aug 2020 13:12:47

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '36.5' C	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Oral (Oral)'	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	



US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '93'	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'bpm'	(b) (4), (b) (6) System	21 Aug 2020 13:12:47

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '14'	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'breaths/min'	(b) (4), (b) (6) System	21 Aug 2020 13:12:47

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '110'	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 13:12:47

US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '65'	Stella Yoon (b) (4)	21 Aug 2020 13:12:47
	(b) (4)	



US3022233

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 13:12:47

US3022233

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:09

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User closed query 'Per CDM: Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be recorded as "No" at Visit 1 Day 1. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:13:19
Query 'Per CDM: Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be recorded as "No" at Visit 1 Day 1. Please update accordingly. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:42:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:42:29
User opened query 'Per CDM: Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be recorded as "No" at Visit 1 Day 1. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 16:22:07
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 13:12:53
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:42:29
User entered '20 Aug 2020'	Stella Yoon (b) (4)	21 Aug 2020 13:12:53
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:57:09

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User closed query 'Per CDM: If Screening visit and Dosing are done on the same day (20 Aug 2020) then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "NO" at V1D1 to avoid duplication. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:50:12
Query 'Per CDM: If Screening visit and Dosing are done on the same day (20 Aug 2020) then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "NO" at V1D1 to avoid duplication. Please review and update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 13:04:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 13:04:24
User opened query 'Per CDM: If Screening visit and Dosing are done on the same day (20 Aug 2020) then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "NO" at V1D1 to avoid duplication. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 09:37:57
Query 'Per CDM: Per CCGs, when Screening and Visit 1 Day 1 occur on the same day 'Was the pregnancy test performed?' and "Was FSH sample collected?" should be recorded only at Screening and marked as "No" at Visit 1 Day 1 and pregnancy test data should not be recorded on this page. Please review and update Pregnancy test form at Visit 1 Day 1 as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 09:37:35
User opened query 'Per CDM: Per CCGs, when Screening and Visit 1 Day 1 occur on the same day 'Was the pregnancy test performed?' and "Was FSH sample collected?" should be recorded only at Screening and marked as "No" at Visit 1 Day 1 and pregnancy test data should not be recorded on this page. Please review and update Pregnancy test form at Visit 1 Day 1 as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 09:32:24

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:57:09

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: "Is the participant of Childbearing potential?" is marked as "No"; however, pregnancy test data is recorded. Please review, reconcile and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:10:47
Query 'Per CDM: "Is the participant of Childbearing potential?" is marked as "No"; however, pregnancy test data is recorded. Please review, reconcile and update as appropriate, else clarify. Thank you.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:48:14
User opened query 'Per CDM: "Is the participant of Childbearing potential?" is marked as "No"; however, pregnancy test data is recorded. Please review, reconcile and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:03:43
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 13:13:01

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:57:09

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User entered empty; reason for change Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 13:04:24
User entered '20 Aug 2020'		
	Stella Yoon (b) (4)	21 Aug 2020 13:13:01
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:57:09

Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 13:04:24
User entered 'Urine (URINE)'	Stella Yoon (b) (4)	21 Aug 2020 13:13:01
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:57:09

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 13:04:24
User entered 'Negative (NEGATIVE)'	Stella Yoon (b) (4)	21 Aug 2020 13:13:01
	(b) (4)	



US3022233

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:57:09

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 13:13:01
	(b) (4)	

**US3022233**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 13:13:01
	(b) (4)	

**US3022233**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 13:13:01
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:57:09

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 13:13:01

**US3022233**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:57:09**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	20 Aug 2020 22:51:32
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Aug 2020 22:51:32
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

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)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Aug 2020 22:51:32
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32



US3022233

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '20 Aug 2020'	Shanice Bennett (b) (4)	20 Aug 2020 22:51:32
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '18:30'	Shanice Bennett (b) (4)	20 Aug 2020 22:51:32
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered '20 Aug 2020 18:30'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Shanice Bennett (b) (4)	20 Aug 2020 22:51:32
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'ONCE'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:57:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 13:13:18
	(b) (4)	

US3022233

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:57:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 20AUG2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 21AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:14:40
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 20AUG2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 21AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with '20AUG2020 IS THE CORRECT DATE ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:51:34
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 20AUG2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 21AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 11:53:47
User entered '20 Aug 2020'	Stella Yoon (b) (4)	21 Aug 2020 13:13:18
	(b) (4)	



**US3022233**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '17:22'	Stella Yoon (b) (4)	21 Aug 2020 13:13:18
	(b) (4)	

**US3022233**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered '20 Aug 2020 17:22'	(b) (4), (b) (6) System	21 Aug 2020 13:13:18

US3022233

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:57:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 20-AUG-2020 is recorded under Visit 1 Day 1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 10:26:20
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 20-AUG-2020 is recorded under Visit 1 Day 1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with '1F600105996' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 16:15:49
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 20-AUG-2020 is recorded under Visit 1 Day 1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 11:00:15
User closed query 'Per GCL Lab Rec: it appears GCL has this as 21AUG2020 Please confirm the date of 20AUG2020 is for Day 1 or clarify' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:15:21
Query 'Per GCL Lab Rec: it appears GCL has this as 21AUG2020 Please confirm the date of 20AUG2020 is for Day 1 or clarify' answered with 'THE CORRECT DATE IS 20AUG2020' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:52:24
User opened query 'Per GCL Lab Rec: it appears GCL has this as 21AUG2020 Please confirm the date of 20AUG2020 is for Day 1 or clarify' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 18:11:21
User entered '20 Aug 2020'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 13:13:28

**US3022233**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 21:57:09**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	21 Aug 2020 13:13:28

US3022233

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:57:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 13:13:28
	(b) (4)	

**US3022233**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '17:32'	Stella Yoon (b) (4)	21 Aug 2020 13:13:28
	(b) (4)	

**US3022233**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered '20 Aug 2020 17:32'	(b) (4), (b) (6) System	21 Aug 2020 13:13:28

**US3022233**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 21:57:09**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	21 Aug 2020 13:13:28



US3022233

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:57:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 13:13:28
	(b) (4)	

**US3022233**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 13:13:28
	(b) (4)	

**US3022233**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 13:13:28

**US3022233**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 13:13:32
	(b) (4)	

**US3022233**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered '1'	(b) (4), (b) (6) System	21 Aug 2020 13:13:32

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-20T19:01:39', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'e2c5499f-ca42-4f6d-9eb2-27da5902aa9c' User entered 'Yes (Y)'	(b) (4), (b) (6) System	20 Aug 2020 23:02:09
	System	20 Aug 2020 23:02:09

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-20T19:01:49', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'e2c5499f-ca42-4f6d-9eb2-27da5902aa9c' User entered '97.8'	(b) (4), (b) (6) System	20 Aug 2020 23:02:09
	System	20 Aug 2020 23:02:09



US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-20T19:01:54', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'e2c5499f-ca42-4f6d-9eb2-27da5902aa9c'	(b) (4), (b) (6)	
System		20 Aug 2020 23:02:09
User entered 'No (N)'	System	20 Aug 2020 23:02:09

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-20T19:02:05', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'e2c5499f-ca42-4f6d-9eb2-27da5902aa9c' User entered '20 Aug 2020 19:02'	(b) (4), (b) (6) System	20 Aug 2020 23:02:09
	System	20 Aug 2020 23:02:09

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '20 Aug 2020 18:50'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '20 Aug 2020 21:20'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-21T08:07:19', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fd2179f3-eaf0-42fa-b1e2-d6965c157534'	(b) (4), (b) (6) System	21 Aug 2020 12:07:57
User entered 'Yes (Y)'	System	21 Aug 2020 12:07:57

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-21T08:07:38', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fd2179f3-eaf0-42fa-b1e2-d6965c157534' User entered '97.6'	System	21 Aug 2020 12:07:57
	System	21 Aug 2020 12:07:57

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-21T08:07:43', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fd2179f3-eaf0-42fa-b1e2-d6965c157534'	System	21 Aug 2020 12:07:57
User entered 'No (N)'	System	21 Aug 2020 12:07:57



US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-21T08:07:52', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fd2179f3-eaf0-42fa-b1e2-d6965c157534' User entered '21 Aug 2020 08:07'	System	21 Aug 2020 12:07:57
	System	21 Aug 2020 12:07:57

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '20 Aug 2020 22:15'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

**US3022233**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 2'	System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-22T08:09:46', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'bf25777e-1eaf-4787-a771-69d489f73b10'	(b) (4), (b) (6)	
	System	22 Aug 2020 12:10:20
User entered 'Yes (Y)'	System	22 Aug 2020 12:10:20

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-22T08:10:05', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'bf25777e-1eaf-4787-a771-69d489f73b10' User entered '97.0'	System	22 Aug 2020 12:10:20
	System	22 Aug 2020 12:10:20

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-22T08:10:09', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'bf25777e-1eaf-4787-a771-69d489f73b10'	(b) (4), (b) (6)	
System		22 Aug 2020 12:10:20
User entered 'No (N)'	System	22 Aug 2020 12:10:20

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-22T08:10:17', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'bf25777e-1eaf-4787-a771-69d489f73b10' User entered '22 Aug 2020 08:10'	System	22 Aug 2020 12:10:20
	System	22 Aug 2020 12:10:20



US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 22:51:32
User entered 'Day 3'	System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-23T00:38:26', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '2d9bea6c-f98d-4e37-b2f7-5fec73d27ae3' User entered 'Yes (Y)'	System	23 Aug 2020 04:38:48
	System	23 Aug 2020 04:38:48

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-23T00:38:34', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '2d9bea6c-f98d-4e37-b2f7-5fec73d27ae3' User entered '96.2'	System	23 Aug 2020 04:38:48
	System	23 Aug 2020 04:38:48

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-23T00:38:39', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '2d9bea6c-f98d-4e37-b2f7-5fec73d27ae3'	(b) (4), (b) (6)	
	System	23 Aug 2020 04:38:48
User entered 'No (N)'	System	23 Aug 2020 04:38:48

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-23T00:38:45', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '2d9bea6c-f98d-4e37-b2f7-5fec73d27ae3' User entered '23 Aug 2020 00:38'	System	23 Aug 2020 04:38:48
	System	23 Aug 2020 04:38:48

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32



US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 22:51:32
User entered 'Day 4'	System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T00:05:32', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '5bc51bec-beb0-40c1-916b-df5afd0c5ae8' User entered 'Yes (Y)'	System	24 Aug 2020 04:06:07
	System	24 Aug 2020 04:06:07

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T00:05:55', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '5bc51bec-beb0-40c1-916b-df5afd0c5ae8' User entered '97.3'	System	24 Aug 2020 04:06:07
	System	24 Aug 2020 04:06:07

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T00:06:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '5bc51bec-beb0-40c1-916b-df5afd0c5ae8' User entered 'No (N)'	System	24 Aug 2020 04:06:07
	System	24 Aug 2020 04:06:07

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T00:06:05', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '5bc51bec-beb0-40c1-916b-df5afd0c5ae8' User entered '24 Aug 2020 00:06'	System	24 Aug 2020 04:06:07
	System	24 Aug 2020 04:06:07

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32



US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 22:51:32
User entered 'Day 5'	System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T16:51:21', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a4afd05a-5834-45b7-ae41-53a70f01a187' User entered 'Yes (Y)'	System	24 Aug 2020 20:53:10
	System	24 Aug 2020 20:53:10

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T16:52:55', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a4afd05a-5834-45b7-ae41-53a70f01a187' User entered '98.2'	System	24 Aug 2020 20:53:10
	System	24 Aug 2020 20:53:10

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T16:52:58', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a4afd05a-5834-45b7-ae41-53a70f01a187'	(b) (4), (b) (6)	
	System	24 Aug 2020 20:53:10
User entered 'No (N)'	System	24 Aug 2020 20:53:10

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T16:53:06', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a4afd05a-5834-45b7-ae41-53a70f01a187' User entered '24 Aug 2020 16:53'	System	24 Aug 2020 20:53:10
	System	24 Aug 2020 20:53:10

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 6'	System	20 Aug 2020 22:51:32



US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-25T17:08:42', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'ce6c91b4-a6f7-4e45-b478-f82eec6bc433'	(b) (4), (b) (6)	
	System	25 Aug 2020 21:08:57
User entered 'Yes (Y)'	System	25 Aug 2020 21:08:57

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-25T17:08:47', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'ce6c91b4-a6f7-4e45-b478-f82eec6bc433' User entered '97.6'	(b) (4), (b) (6) System	25 Aug 2020 21:08:57
	System	25 Aug 2020 21:08:57

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-25T17:08:49', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'ce6c91b4-a6f7-4e45-b478-f82eec6bc433'	(b) (4), (b) (6)	
	System	25 Aug 2020 21:08:57
User entered 'No (N)'	System	25 Aug 2020 21:08:57

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-25T17:08:56', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'ce6c91b4-a6f7-4e45-b478-f82eec6bc433'	(b) (4), (b) (6)	
	System	25 Aug 2020 21:08:57
User entered '25 Aug 2020 17:08'	System	25 Aug 2020 21:08:57

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 22:51:32
User entered 'Day 7'	System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-26T15:59:15', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '3f612d14-f039-4d73-8746-908eb687f558'	(b) (4), (b) (6)	
	System	26 Aug 2020 19:59:32
User entered 'Yes (Y)'	System	26 Aug 2020 19:59:32



US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-26T15:59:22', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '3f612d14-f039-4d73-8746-908eb687f558' User entered '97.4'	System	26 Aug 2020 19:59:32
	System	26 Aug 2020 19:59:32

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-26T15:59:24', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '3f612d14-f039-4d73-8746-908eb687f558'	(b) (4), (b) (6) System	26 Aug 2020 19:59:32
User entered 'No (N)'	System	26 Aug 2020 19:59:32

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-26T15:59:28', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '3f612d14-f039-4d73-8746-908eb687f558' User entered '26 Aug 2020 15:59'	System	26 Aug 2020 19:59:32
	System	26 Aug 2020 19:59:32

US3022233

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-20T19:02:18', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'cddbffcc-23fc-46c1-b3c9-9351778dafc7'	(b) (4), (b) (6)	20 Aug 2020 23:02:45
User entered 'None (1)'	System	20 Aug 2020 23:02:45

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-20T19:02:21', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'cddbffcc-23fc-46c1-b3c9-9351778dafc7'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Aug 2020 23:02:45
	System	20 Aug 2020 23:02:45



US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-20T19:02:25', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'cddbffcc-23fc-46c1-b3c9-9351778dafc7'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Aug 2020 23:02:45

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-20T19:02:34', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'cddbffcc-23fc-46c1-b3c9-9351778dafc7'	(b) (4), (b) (6)	20 Aug 2020 23:02:45
User entered 'None (1)'	System	20 Aug 2020 23:02:45

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-20T19:02:40', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'cddbffcc-23fc-46c1-b3c9-9351778dafc7'	(b) (4), (b) (6)	
	System	20 Aug 2020 23:02:45
User entered '20 Aug 2020 19:02'	System	20 Aug 2020 23:02:45

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '20 Aug 2020 18:50'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '20 Aug 2020 21:20'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-21T08:07:58', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a55ebcf4-87eb-4b2a-8c2e-1fa764a74efd' User entered 'None (1)'	System	21 Aug 2020 12:08:25
	System	21 Aug 2020 12:08:25

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-21T08:08:01', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a55ebcf4-87eb-4b2a-8c2e-1fa764a74efd' User entered 'No (N)'	System	21 Aug 2020 12:08:25
	System	21 Aug 2020 12:08:25



US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-21T08:08:05', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a55ebcf4-87eb-4b2a-8c2e-1fa764a74efd' User entered 'No (N)'	System	21 Aug 2020 12:08:25
	System	21 Aug 2020 12:08:25

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-21T08:08:13', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a55ebcf4-87eb-4b2a-8c2e-1fa764a74efd' User entered 'None (1)'	System	21 Aug 2020 12:08:25
	System	21 Aug 2020 12:08:25

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-21T08:08:18', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a55ebcf4-87eb-4b2a-8c2e-1fa764a74efd' User entered '21 Aug 2020 08:08'	System	21 Aug 2020 12:08:25
	System	21 Aug 2020 12:08:25

**US3022233**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '20 Aug 2020 22:15'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

**US3022233**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 2'	System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-22T08:10:23', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '09eb9c28-6a14-403a-b777-6408adbe29e7' User entered 'None (1)'	System	22 Aug 2020 12:10:58
	System	22 Aug 2020 12:10:58

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-22T08:10:51', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '09eb9c28-6a14-403a-b777-6408adbe29e7' User entered 'No (N)'	System	22 Aug 2020 12:10:58
	System	22 Aug 2020 12:10:58



US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-22T08:10:30', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '09eb9c28-6a14-403a-b777-6408adbe29e7' User entered 'No (N)'	System	22 Aug 2020 12:10:58
	System	22 Aug 2020 12:10:58

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-22T08:10:43', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '09eb9c28-6a14-403a-b777-6408adbe29e7' User entered 'None (1)'	System	22 Aug 2020 12:10:58
	System	22 Aug 2020 12:10:58

**US3022233**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-22T08:10:54', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '09eb9c28-6a14-403a-b777-6408adbe29e7' User entered '22 Aug 2020 08:10'	System	22 Aug 2020 12:10:58
	System	22 Aug 2020 12:10:58

**US3022233**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 3'	System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-23T00:38:57', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'c3aad8fb-ee75-49c6-8245-ab555ed04c24' User entered 'None (1)'	System	23 Aug 2020 04:39:13
	System	23 Aug 2020 04:39:13

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-23T00:38:55', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'c3aad8fb-ee75-49c6-8245-ab555ed04c24' User entered 'No (N)'	System	23 Aug 2020 04:39:13
	System	23 Aug 2020 04:39:13



US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-23T00:39:01', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'c3aad8fb-ee75-49c6-8245-ab555ed04c24' User entered 'No (N)'	System	23 Aug 2020 04:39:13
	System	23 Aug 2020 04:39:13

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-23T00:39:07', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'c3aad8fb-ee75-49c6-8245-ab555ed04c24' User entered 'None (1)'	(b) (4), (b) (6) System	23 Aug 2020 04:39:13
	System	23 Aug 2020 04:39:13

**US3022233**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-23T00:39:11', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'c3aad8fb-ee75-49c6-8245-ab555ed04c24' User entered '23 Aug 2020 00:39'	System	23 Aug 2020 04:39:13
	System	23 Aug 2020 04:39:13

**US3022233**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

**US3022233**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 4'	System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T00:06:20', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '05654715-db3e-40db-9bcb-dd5822448ac8'	(b) (4), (b) (6) System	24 Aug 2020 04:06:33
User entered 'None (1)'	System	24 Aug 2020 04:06:33

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T00:06:18', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '05654715-db3e-40db-9bcb-dd5822448ac8' User entered 'No (N)'	System	24 Aug 2020 04:06:33
	System	24 Aug 2020 04:06:33



US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T00:06:23', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '05654715-db3e-40db-9bcb-dd5822448ac8'	System	24 Aug 2020 04:06:33
User entered 'No (N)'	System	24 Aug 2020 04:06:33

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T00:06:29', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '05654715-db3e-40db-9bcb-dd5822448ac8'	(b) (4), (b) (6)	
	System	24 Aug 2020 04:06:33
User entered 'None (1)'	System	24 Aug 2020 04:06:33

**US3022233**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T00:06:31', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '05654715-db3e-40db-9bcb-dd5822448ac8' User entered '24 Aug 2020 00:06'	System	24 Aug 2020 04:06:33
	System	24 Aug 2020 04:06:33

**US3022233**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 5'	System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T16:53:10', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '6e7f7750-5b8e-4055-8276-32493e142a65'	(b) (4), (b) (6)	
	System	24 Aug 2020 20:53:24
User entered 'None (1)'	System	24 Aug 2020 20:53:24

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T16:53:13', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '6e7f7750-5b8e-4055-8276-32493e142a65'	System	24 Aug 2020 20:53:24
User entered 'No (N)'	System	24 Aug 2020 20:53:24



US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T16:53:16', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '6e7f7750-5b8e-4055-8276-32493e142a65' User entered 'No (N)'	System	24 Aug 2020 20:53:24
	System	24 Aug 2020 20:53:24

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T16:53:19', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '6e7f7750-5b8e-4055-8276-32493e142a65'	(b) (4), (b) (6)	
	System	24 Aug 2020 20:53:24
User entered 'None (1)'	System	24 Aug 2020 20:53:24

**US3022233**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T16:53:21', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '6e7f7750-5b8e-4055-8276-32493e142a65' User entered '24 Aug 2020 16:53'	System	24 Aug 2020 20:53:24
	System	24 Aug 2020 20:53:24

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

**US3022233**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 6'	System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-25T17:08:59', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '913bf741-6535-4270-ba05-c1a6048cd80a' User entered 'None (1)'	System	25 Aug 2020 21:09:16
	System	25 Aug 2020 21:09:16

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-25T17:09:03', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '913bf741-6535-4270-ba05-c1a6048cd80a' User entered 'No (N)'	System	25 Aug 2020 21:09:16
	System	25 Aug 2020 21:09:16



US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-25T17:09:06', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '913bf741-6535-4270-ba05-c1a6048cd80a' User entered 'No (N)'	System	25 Aug 2020 21:09:16
	System	25 Aug 2020 21:09:16

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-25T17:09:10', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '913bf741-6535-4270-ba05-c1a6048cd80a' User entered 'None (1)'	System	25 Aug 2020 21:09:16
	System	25 Aug 2020 21:09:16

**US3022233**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-25T17:09:13', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '913bf741-6535-4270-ba05-c1a6048cd80a' User entered '25 Aug 2020 17:09'	System	25 Aug 2020 21:09:16
	System	25 Aug 2020 21:09:16

**US3022233**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 7'	System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-26T15:59:47', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '6e155cfa-2fed-40e0-8aa2-a49e759e6d50'	(b) (4), (b) (6) System	26 Aug 2020 20:00:12
User entered 'None (1)'	System	26 Aug 2020 20:00:12

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-26T16:00:02', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '6e155cfa-2fed-40e0-8aa2-a49e759e6d50' User entered 'No (N)'	System	26 Aug 2020 20:00:12
	System	26 Aug 2020 20:00:12



US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-26T16:00:04', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '6e155cfa-2fed-40e0-8aa2-a49e759e6d50' User entered 'No (N)'	System	26 Aug 2020 20:00:12
	System	26 Aug 2020 20:00:12

US3022233

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-26T16:00:06', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '6e155cfa-2fed-40e0-8aa2-a49e759e6d50'	(b) (4), (b) (6)	
	System	26 Aug 2020 20:00:12
User entered 'None (1)'	System	26 Aug 2020 20:00:12

**US3022233**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-26T16:00:09', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '6e155cfa-2fed-40e0-8aa2-a49e759e6d50' User entered '26 Aug 2020 16:00'	System	26 Aug 2020 20:00:12
	System	26 Aug 2020 20:00:12

**US3022233**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

**US3022233**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 22:51:32

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-20T19:02:46', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b9b3fab1-d34c-4a78-9d42-1df7f9e2ac37' User entered 'None (0)'	System	20 Aug 2020 23:03:10
	System	20 Aug 2020 23:03:10

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-20T19:02:48', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b9b3fab1-d34c-4a78-9d42-1df7f9e2ac37' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 23:03:10
	System	20 Aug 2020 23:03:10



US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-20T19:02:51', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b9b3fab1-d34c-4a78-9d42-1df7f9e2ac37' User entered 'None (0)'	System	20 Aug 2020 23:03:10
	System	20 Aug 2020 23:03:10

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-20T19:02:53', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b9b3fab1-d34c-4a78-9d42-1df7f9e2ac37' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 23:03:10
	System	20 Aug 2020 23:03:10

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-20T19:02:55', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b9b3fab1-d34c-4a78-9d42-1df7f9e2ac37' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 23:03:10
	System	20 Aug 2020 23:03:10

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-20T19:02:58', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b9b3fab1-d34c-4a78-9d42-1df7f9e2ac37' User entered 'None (0)'	System	20 Aug 2020 23:03:10
	System	20 Aug 2020 23:03:10

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-20T19:03:01', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b9b3fab1-d34c-4a78-9d42-1df7f9e2ac37'	(b) (4), (b) (6)	
	System	20 Aug 2020 23:03:10
User entered 'No (N)'	System	20 Aug 2020 23:03:10

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-20T19:03:07', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b9b3fab1-d34c-4a78-9d42-1df7f9e2ac37' User entered '20 Aug 2020 19:03'	(b) (4), (b) (6) System	20 Aug 2020 23:03:10
	System	20 Aug 2020 23:03:10

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '20 Aug 2020 18:50'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '20 Aug 2020 21:20'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32



US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 22:51:32

**US3022233**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:09**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-21T08:08:26', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '289a4a63-a9c5-4514-8607-1ccf7aeeab62' User entered 'None (0)'	System	21 Aug 2020 12:08:53
	System	21 Aug 2020 12:08:53

**US3022233**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:09**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-21T08:08:29', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '289a4a63-a9c5-4514-8607-1ccf7aeeab62' User entered 'None (0)'	System	21 Aug 2020 12:08:53
	System	21 Aug 2020 12:08:53

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-21T08:08:32', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '289a4a63-a9c5-4514-8607-1ccf7aeeab62' User entered 'None (0)'	System	21 Aug 2020 12:08:53
	System	21 Aug 2020 12:08:53

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-21T08:08:34', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '289a4a63-a9c5-4514-8607-1ccf7aeeab62' User entered 'None (0)'	System	21 Aug 2020 12:08:53
	System	21 Aug 2020 12:08:53

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-21T08:08:37', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '289a4a63-a9c5-4514-8607-1ccf7aeeab62' User entered 'None (0)'	System	21 Aug 2020 12:08:53
	System	21 Aug 2020 12:08:53

**US3022233**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-21T08:08:39', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '289a4a63-a9c5-4514-8607-1ccf7aeeab62' User entered 'None (0)'	System	21 Aug 2020 12:08:53
	System	21 Aug 2020 12:08:53

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-21T08:08:43', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '289a4a63-a9c5-4514-8607-1ccf7aeeab62'	(b) (4), (b) (6)	
	System	21 Aug 2020 12:08:53
User entered 'No (N)'	System	21 Aug 2020 12:08:53



**US3022233**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-21T08:08:47', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '289a4a63-a9c5-4514-8607-1ccf7aeeab62' User entered '21 Aug 2020 08:08'	System	21 Aug 2020 12:08:53
	System	21 Aug 2020 12:08:53

**US3022233**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '20 Aug 2020 22:15'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 2'	System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-22T08:10:59', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'cd81ad0a-e02c-49b5-9829-72f6405d9d62' User entered 'None (0)'	System	22 Aug 2020 12:11:26
	System	22 Aug 2020 12:11:26

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-22T08:11:02', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'cd81ad0a-e02c-49b5-9829-72f6405d9d62' User entered 'None (0)'	System	22 Aug 2020 12:11:26
	System	22 Aug 2020 12:11:26

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-22T08:11:05', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'cd81ad0a-e02c-49b5-9829-72f6405d9d62' User entered 'None (0)'	System	22 Aug 2020 12:11:26
	System	22 Aug 2020 12:11:26

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-22T08:11:08', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'cd81ad0a-e02c-49b5-9829-72f6405d9d62' User entered 'None (0)'	System	22 Aug 2020 12:11:26
	System	22 Aug 2020 12:11:26



US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-22T08:11:11', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'cd81ad0a-e02c-49b5-9829-72f6405d9d62' User entered 'None (0)'	System	22 Aug 2020 12:11:26
	System	22 Aug 2020 12:11:26

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-22T08:11:14', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'cd81ad0a-e02c-49b5-9829-72f6405d9d62' User entered 'None (0)'	System	22 Aug 2020 12:11:26
	System	22 Aug 2020 12:11:26

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:09

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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-22T08:11:18', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'cd81ad0a-e02c-49b5-9829-72f6405d9d62' User entered 'No (N)'	System	22 Aug 2020 12:11:26
	System	22 Aug 2020 12:11:26

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-22T08:11:24', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'cd81ad0a-e02c-49b5-9829-72f6405d9d62' User entered '22 Aug 2020 08:11'	System	22 Aug 2020 12:11:26
	System	22 Aug 2020 12:11:26

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 3'	System	20 Aug 2020 22:51:32

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-23T00:39:15', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '87c212dc-c10e-424f-b422-5b5cbefc12f3' User entered 'None (0)'	System	23 Aug 2020 04:39:40
	System	23 Aug 2020 04:39:40



US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-23T00:39:18', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '87c212dc-c10e-424f-b422-5b5cbefc12f3' User entered 'None (0)'	System	23 Aug 2020 04:39:40
	System	23 Aug 2020 04:39:40

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-23T00:39:21', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '87c212dc-c10e-424f-b422-5b5cbefc12f3' User entered 'None (0)'	System	23 Aug 2020 04:39:40
	System	23 Aug 2020 04:39:40

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-23T00:39:25', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '87c212dc-c10e-424f-b422-5b5cbefc12f3' User entered 'None (0)'	System	23 Aug 2020 04:39:40
	System	23 Aug 2020 04:39:40

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-23T00:39:28', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '87c212dc-c10e-424f-b422-5b5cbefc12f3' User entered 'None (0)'	System	23 Aug 2020 04:39:40
	System	23 Aug 2020 04:39:40

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-23T00:39:30', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '87c212dc-c10e-424f-b422-5b5cbefc12f3' User entered 'None (0)'	System	23 Aug 2020 04:39:40
	System	23 Aug 2020 04:39:40

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:09

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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-23T00:39:35', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '87c212dc-c10e-424f-b422-5b5cbefc12f3' User entered 'No (N)'	System	23 Aug 2020 04:39:40
	System	23 Aug 2020 04:39:40

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-23T00:39:38', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '87c212dc-c10e-424f-b422-5b5cbefc12f3' User entered '23 Aug 2020 00:39'	(b) (4), (b) (6) System	23 Aug 2020 04:39:40
	System	23 Aug 2020 04:39:40

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32



**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 4'	System	20 Aug 2020 22:51:32

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T00:06:37', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'c5de7093-9450-4ede-bbcc-520d6520f452' User entered 'None (0)'	System	24 Aug 2020 04:06:57
	System	24 Aug 2020 04:06:57

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T00:06:39', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'c5de7093-9450-4ede-bbcc-520d6520f452' User entered 'None (0)'	System	24 Aug 2020 04:06:57
	System	24 Aug 2020 04:06:57

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T00:06:42', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'c5de7093-9450-4ede-bbcc-520d6520f452' User entered 'None (0)'	System	24 Aug 2020 04:06:57
	System	24 Aug 2020 04:06:57

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T00:06:44', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'c5de7093-9450-4ede-bbcc-520d6520f452' User entered 'None (0)'	System	24 Aug 2020 04:06:57
	System	24 Aug 2020 04:06:57

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T00:06:47', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'c5de7093-9450-4ede-bbcc-520d6520f452' User entered 'None (0)'	System	24 Aug 2020 04:06:57
	System	24 Aug 2020 04:06:57

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T00:06:50', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'c5de7093-9450-4ede-bbcc-520d6520f452' User entered 'None (0)'	System	24 Aug 2020 04:06:57
	System	24 Aug 2020 04:06:57



US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:09

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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T00:06:53', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'c5de7093-9450-4ede-bbcc-520d6520f452' User entered 'No (N)'	System	24 Aug 2020 04:06:57
	System	24 Aug 2020 04:06:57

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T00:06:56', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'c5de7093-9450-4ede-bbcc-520d6520f452' User entered '24 Aug 2020 00:06'	(b) (4), (b) (6) System	24 Aug 2020 04:06:57
	System	24 Aug 2020 04:06:57

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 5'	System	20 Aug 2020 22:51:32

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T16:53:25', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '56daba5b-85bc-43e7-b55f-cb90e7509c2b' User entered 'None (0)'	System	24 Aug 2020 20:53:47
	System	24 Aug 2020 20:53:47

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T16:53:27', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '56daba5b-85bc-43e7-b55f-cb90e7509c2b' User entered 'None (0)'	System	24 Aug 2020 20:53:47
	System	24 Aug 2020 20:53:47

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T16:53:29', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '56daba5b-85bc-43e7-b55f-cb90e7509c2b' User entered 'None (0)'	System	24 Aug 2020 20:53:47
	System	24 Aug 2020 20:53:47



US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T16:53:31', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '56daba5b-85bc-43e7-b55f-cb90e7509c2b' User entered 'None (0)'	System	24 Aug 2020 20:53:47
	System	24 Aug 2020 20:53:47

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T16:53:33', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '56daba5b-85bc-43e7-b55f-cb90e7509c2b' User entered 'None (0)'	System	24 Aug 2020 20:53:47
	System	24 Aug 2020 20:53:47

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T16:53:35', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '56daba5b-85bc-43e7-b55f-cb90e7509c2b' User entered 'None (0)'	System	24 Aug 2020 20:53:47
	System	24 Aug 2020 20:53:47

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:09

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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T16:53:40', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '56daba5b-85bc-43e7-b55f-cb90e7509c2b' User entered 'No (N)'	System	24 Aug 2020 20:53:47
	System	24 Aug 2020 20:53:47

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-24T16:53:45', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '56daba5b-85bc-43e7-b55f-cb90e7509c2b' User entered '24 Aug 2020 16:53'	System	24 Aug 2020 20:53:47
	System	24 Aug 2020 20:53:47

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 6'	System	20 Aug 2020 22:51:32



US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-25T17:09:17', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'e0557523-3512-4787-a126-66e009022b91' User entered 'None (0)'	System	25 Aug 2020 21:09:35
	System	25 Aug 2020 21:09:35

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-25T17:09:19', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'e0557523-3512-4787-a126-66e009022b91'	(b) (4), (b) (6)	
User entered 'None (0)'	System	25 Aug 2020 21:09:35

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-25T17:09:21', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'e0557523-3512-4787-a126-66e009022b91'	(b) (4), (b) (6)	
System		25 Aug 2020 21:09:35
User entered 'None (0)'	System	25 Aug 2020 21:09:35

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-25T17:09:23', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'e0557523-3512-4787-a126-66e009022b91' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 21:09:35
	System	25 Aug 2020 21:09:35

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-25T17:09:25', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'e0557523-3512-4787-a126-66e009022b91' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 21:09:35
	System	25 Aug 2020 21:09:35

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-25T17:09:26', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'e0557523-3512-4787-a126-66e009022b91' User entered 'None (0)'	System	25 Aug 2020 21:09:35
	System	25 Aug 2020 21:09:35

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:09

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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-25T17:09:29', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'e0557523-3512-4787-a126-66e009022b91'	(b) (4), (b) (6)	
	System	25 Aug 2020 21:09:35
User entered 'No (N)'	System	25 Aug 2020 21:09:35

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-25T17:09:32', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'e0557523-3512-4787-a126-66e009022b91' User entered '25 Aug 2020 17:09'	(b) (4), (b) (6) System	25 Aug 2020 21:09:35
	System	25 Aug 2020 21:09:35



**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 7'	System	20 Aug 2020 22:51:32

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-26T16:00:13', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '01082285-8ddb-42e5-a198-b2dff5e04415' User entered 'None (0)'	System	26 Aug 2020 20:01:09
	System	26 Aug 2020 20:01:09

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-26T16:00:23', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '01082285-8ddb-42e5-a198-b2dff5e04415' User entered 'None (0)'	System	26 Aug 2020 20:01:09
	System	26 Aug 2020 20:01:09

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-26T16:00:25', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '01082285-8ddb-42e5-a198-b2dff5e04415' User entered 'None (0)'	System	26 Aug 2020 20:01:09
	System	26 Aug 2020 20:01:09

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-26T16:00:31', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '01082285-8ddb-42e5-a198-b2dff5e04415' User entered 'None (0)'	System	26 Aug 2020 20:01:09
	System	26 Aug 2020 20:01:09

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-26T16:00:33', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '01082285-8ddb-42e5-a198-b2dff5e04415' User entered 'None (0)'	System	26 Aug 2020 20:01:09
	System	26 Aug 2020 20:01:09



**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-26T16:00:56', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '01082285-8ddb-42e5-a198-b2dff5e04415' User entered 'None (0)'	System	26 Aug 2020 20:01:09
	System	26 Aug 2020 20:01:09

US3022233

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:09

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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-26T16:00:59', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '01082285-8ddb-42e5-a198-b2dff5e04415' User entered 'No (N)'	System	26 Aug 2020 20:01:09
	System	26 Aug 2020 20:01:09

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-08-26T16:01:04', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '01082285-8ddb-42e5-a198-b2dff5e04415' User entered '26 Aug 2020 16:01'	System	26 Aug 2020 20:01:09
	System	26 Aug 2020 20:01:09

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 22:51:32

**US3022233**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	24 Sep 2020 20:45:16
	(b) (4)	

US3022233

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '27 Aug 2020'	Chevon Roberts (b) (4)	24 Sep 2020 20:45:16
	(b) (4)	

**US3022233**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Chevon Roberts (b) (4)	24 Sep 2020 20:45:16
	(b) (4)	



**US3022233**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	24 Feb 2021 00:21:14
User entered empty.	Chevon Roberts (b) (4) (b) (4)	24 Sep 2020 20:45:16

US3022233

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	24 Sep 2020 20:45:19
	(b) (4)	

**US3022233**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'I'	(b) (4), (b) (6) System	24 Sep 2020 20:45:19

**US3022233**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	24 Sep 2020 20:45:35
	(b) (4)	

**US3022233**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '03 Sep 2020'	Chevon Roberts (b) (4)	24 Sep 2020 20:45:35
	(b) (4)	

US3022233

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Chevon Roberts (b) (4)	24 Sep 2020 20:45:35
	(b) (4)	

**US3022233**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	24 Sep 2020 20:45:35
	(b) (4)	

US3022233

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	24 Sep 2020 20:45:38
	(b) (4)	



**US3022233**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered '1'	(b) (4), (b) (6) System	24 Sep 2020 20:45:38

**US3022233**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	24 Sep 2020 20:45:51
	(b) (4)	

**US3022233**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '11 Sep 2020'	Chevon Roberts (b) (4)	24 Sep 2020 20:45:51
	(b) (4)	

US3022233

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Chevon Roberts (b) (4)	24 Sep 2020 20:45:51
	(b) (4)	

US3022233

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:57:09

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	24 Sep 2020 20:45:51
	(b) (4)	

US3022233

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	24 Sep 2020 20:45:54
	(b) (4)	

**US3022233**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered '1'	(b) (4), (b) (6) System	24 Sep 2020 20:45:54

US3022233

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:57:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16NOV2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 3 Day 57 Visit on Immunogenicity Assessment page.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 05:30:28
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16NOV2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 3 Day 57 Visit on Immunogenicity Assessment page.'	(b) (4), (b) (6)	03 Dec 2020 20:49:07
answered with 'updated' (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16NOV2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 3 Day 57 Visit on Immunogenicity Assessment page.'	(b) (4), (b) (6)	02 Dec 2020 09:57:13
(Site from DM).		
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:48:17



**US3022233**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:48:17

US3022233

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Sep 2020 21:48:17

**US3022233**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'VISIT2'	(b) (4), (b) (6) System	24 Sep 2020 21:48:17

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	24 Sep 2020 21:50:19

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:50:19

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:50:19

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '15:52'	(b) (4), (b) (6)	24 Sep 2020 21:50:19

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered '24 Sep 2020 15:52'	(b) (4), (b) (6) System	24 Sep 2020 21:50:19



US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '36.9' C	(b) (4), (b) (6)	24 Sep 2020 21:50:19

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Sep 2020 21:50:19

**US3022233**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 21:57:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:50:19

**US3022233**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 21:57:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '86'	(b) (4), (b) (6)	24 Sep 2020 21:50:19

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'bpm'	(b) (4), (b) (6) System	24 Sep 2020 21:50:19

**US3022233**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '15'	(b) (4), (b) (6)	24 Sep 2020 21:50:19

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'breaths/min'	(b) (4), (b) (6) System	24 Sep 2020 21:50:19

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '110'	(b) (4), (b) (6)	24 Sep 2020 21:50:19



US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'mmHg'	(b) (4), (b) (6) System	24 Sep 2020 21:50:19

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '70'	(b) (4), (b) (6)	24 Sep 2020 21:50:19

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'mmHg'	(b) (4), (b) (6) System	24 Sep 2020 21:50:19

**US3022233**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 21:57:09**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	24 Sep 2020 21:55:58

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:55:58

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:55:58

**US3022233**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '17:08'	(b) (4), (b) (6)	24 Sep 2020 21:55:58

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered '24 Sep 2020 17:08'	(b) (4), (b) (6) System	24 Sep 2020 21:55:58



US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '36.7' C	(b) (4), (b) (6)	24 Sep 2020 21:55:58

**US3022233**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 21:57:09**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Sep 2020 21:55:58

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:55:58

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '80'	(b) (4), (b) (6)	24 Sep 2020 21:55:58

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'bpm'	(b) (4), (b) (6) System	24 Sep 2020 21:55:58

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '16'	(b) (4), (b) (6)	24 Sep 2020 21:55:58

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'breaths/min'	(b) (4), (b) (6) System	24 Sep 2020 21:55:58

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '118'	(b) (4), (b) (6)	24 Sep 2020 21:55:58



US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'mmHg'	(b) (4), (b) (6) System	24 Sep 2020 21:55:58

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '84'	(b) (4), (b) (6)	24 Sep 2020 21:55:58

US3022233

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'mmHg'	(b) (4), (b) (6) System	24 Sep 2020 21:55:58

**US3022233**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:57:09**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:50:42

**US3022233**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:50:42

US3022233

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:57:09

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User closed query 'Per CDM: "Is the participant of Childbearing potential?" is marked as "No"; however, pregnancy test data is recorded. Please review, reconcile and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:11:19
Query 'Per CDM: "Is the participant of Childbearing potential?" is marked as "No"; however, pregnancy test data is recorded. Please review, reconcile and update as appropriate, else clarify. Thank you.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:44:24
User opened query 'Per CDM: "Is the participant of Childbearing potential?" is marked as "No"; however, pregnancy test data is recorded. Please review, reconcile and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:03:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:51:43

**US3022233**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:51:43

**US3022233**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Urine (URINE)'	(b) (4), (b) (6)	24 Sep 2020 21:51:43



**US3022233**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	24 Sep 2020 21:51:43

US3022233

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:57:09

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:51:43

**US3022233**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:51:43

**US3022233**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:51:43

US3022233

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered empty.	(b) (4), (b) (6) System	24 Sep 2020 21:51:43

US3022233

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	24 Sep 2020 20:46:19
	(b) (4)	

US3022233

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	24 Sep 2020 20:46:19
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

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)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	24 Sep 2020 20:46:19
	(b) (4)	



US3022233

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '24 Sep 2020'	Chevon Roberts (b) (4)	24 Sep 2020 20:46:19
	(b) (4)	

US3022233

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '16:38'	Chevon Roberts (b) (4)	24 Sep 2020 20:46:19
	(b) (4)	

**US3022233**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered '24 Sep 2020 16:38'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Chevon Roberts (b) (4)	24 Sep 2020 20:46:19
	(b) (4)	

US3022233

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'ONCE'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:57:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:52:20



US3022233

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:57:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:52:20

**US3022233**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '16:01'	(b) (4), (b) (6)	24 Sep 2020 21:52:20

**US3022233**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered '24 Sep 2020 16:01'	(b) (4), (b) (6) System	24 Sep 2020 21:52:20

US3022233

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:57:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 21:53:47

**US3022233**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 21:57:09**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	24 Sep 2020 21:53:47

US3022233

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:57:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:53:47

**US3022233**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '16:10'	(b) (4), (b) (6)	24 Sep 2020 21:53:47

**US3022233**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered '24 Sep 2020 16:10'	(b) (4), (b) (6) System	24 Sep 2020 21:53:47



**US3022233**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 21:57:09**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	24 Sep 2020 21:53:47

US3022233

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:57:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 21:53:47

**US3022233**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 21:53:47

**US3022233**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered empty.	(b) (4), (b) (6) System	24 Sep 2020 21:53:47

US3022233

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 21:53:57

**US3022233**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered '1'	(b) (4), (b) (6) System	24 Sep 2020 21:53:57

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-24T17:10:56', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '6c1936f0-93d7-4a56-99be-74df89623d93'	(b) (4), (b) (6)	
	System	24 Sep 2020 21:11:19
User entered 'Yes (Y)'	System	24 Sep 2020 21:11:19



US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-24T17:11:04', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '6c1936f0-93d7-4a56-99be-74df89623d93' User entered '98.0'	(b) (4), (b) (6) System	24 Sep 2020 21:11:19
	System	24 Sep 2020 21:11:19

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-24T17:11:09', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '6c1936f0-93d7-4a56-99be-74df89623d93'	(b) (4), (b) (6)	
System		24 Sep 2020 21:11:19
User entered 'No (N)'	System	24 Sep 2020 21:11:19

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-24T17:11:17', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '6c1936f0-93d7-4a56-99be-74df89623d93'	(b) (4), (b) (6)	
	System	24 Sep 2020 21:11:19
User entered '24 Sep 2020 17:11'	System	24 Sep 2020 21:11:19

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '24 Sep 2020 16:58'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '24 Sep 2020 19:28'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-25T08:19:30', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '50f17f99-5a14-4c83-8d71-de9a55fa34e2'	(b) (4), (b) (6)	
	System	25 Sep 2020 12:20:44
User entered 'Yes (Y)'	System	25 Sep 2020 12:20:44

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-25T08:20:31', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '50f17f99-5a14-4c83-8d71-de9a55fa34e2' User entered '96.2'	(b) (4), (b) (6) System	25 Sep 2020 12:20:44
	System	25 Sep 2020 12:20:44



US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-25T08:20:34', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '50f17f99-5a14-4c83-8d71-de9a55fa34e2'	(b) (4), (b) (6)	
	System	25 Sep 2020 12:20:44
User entered 'No (N)'	System	25 Sep 2020 12:20:44

**US3022233**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-25T08:20:41', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '50f17f99-5a14-4c83-8d71-de9a55fa34e2' User entered '25 Sep 2020 08:20'	(b) (4), (b) (6) System	25 Sep 2020 12:20:44
	System	25 Sep 2020 12:20:44

**US3022233**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '24 Sep 2020 20:23'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '25 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 2'	System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T00:01:18', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b495cc30-2eca-44c2-a558-2be0b7cccd6'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	26 Sep 2020 04:02:22
	System	26 Sep 2020 04:02:22

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T00:01:26', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b495cc30-2eca-44c2-a558-2be0b7cccd6' User entered '98.6'	System	26 Sep 2020 04:02:22
	System	26 Sep 2020 04:02:22

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T00:01:30', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b495cc30-2eca-44c2-a558-2be0b7cccd6'	(b) (4), (b) (6)	
User entered 'No (N)'	System	26 Sep 2020 04:02:22



**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T00:01:32', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b495cc30-2eca-44c2-a558-2be0b7cccd6'	System	26 Sep 2020 04:02:22
User entered '26 Sep 2020 00:01'	System	26 Sep 2020 04:02:22

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '25 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 3'	System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T14:01:48', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '0f8bd099-74f0-4a9b-a1ce-1ace7f6593ca' User entered 'Yes (Y)'	System	26 Sep 2020 18:02:06
	System	26 Sep 2020 18:02:06

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T14:01:56', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '0f8bd099-74f0-4a9b-a1ce-1ace7f6593ca' User entered '98.0'	(b) (4), (b) (6) System	26 Sep 2020 18:02:06
	System	26 Sep 2020 18:02:06

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T14:01:59', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '0f8bd099-74f0-4a9b-a1ce-1ace7f6593ca' User entered 'No (N)'	System	26 Sep 2020 18:02:06
	System	26 Sep 2020 18:02:06

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T14:02:02', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '0f8bd099-74f0-4a9b-a1ce-1ace7f6593ca' User entered '26 Sep 2020 14:02'	System	26 Sep 2020 18:02:06
	System	26 Sep 2020 18:02:06



**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 4'	System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-28T06:14:23', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '5946371c-f1e4-4a53-b794-511383777b7e' User entered 'Yes (Y)'	System	28 Sep 2020 10:14:48
	System	28 Sep 2020 10:14:48

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-28T06:14:38', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '5946371c-f1e4-4a53-b794-511383777b7e' User entered '98.0'	System	28 Sep 2020 10:14:48
	System	28 Sep 2020 10:14:48

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-28T06:14:43', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '5946371c-f1e4-4a53-b794-511383777b7e' User entered 'No (N)'	System	28 Sep 2020 10:14:48
	System	28 Sep 2020 10:14:48

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-28T06:14:46', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '5946371c-f1e4-4a53-b794-511383777b7e' User entered '28 Sep 2020 06:14'	System	28 Sep 2020 10:14:48
	System	28 Sep 2020 10:14:48

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19



US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:57:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 5'	System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-29T09:00:33', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '29713757-fc8a-4934-8a88-9e6c7b238da5'	(b) (4), (b) (6)	
	System	29 Sep 2020 13:01:43
User entered 'Yes (Y)'	System	29 Sep 2020 13:01:43

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-29T09:01:36', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '29713757-fc8a-4934-8a88-9e6c7b238da5' User entered '97.6'	System	29 Sep 2020 13:01:43
	System	29 Sep 2020 13:01:43

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-29T09:01:39', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '29713757-fc8a-4934-8a88-9e6c7b238da5'	(b) (4), (b) (6)	
System		29 Sep 2020 13:01:43
User entered 'No (N)'	System	29 Sep 2020 13:01:43

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-29T09:01:42', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '29713757-fc8a-4934-8a88-9e6c7b238da5' User entered '29 Sep 2020 09:01'	System	29 Sep 2020 13:01:43
	System	29 Sep 2020 13:01:43

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19



US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 6'	System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T09:35:30', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'd3d61d90-20c1-4272-b032-3d5c452b5158'	(b) (4), (b) (6)	
	System	30 Sep 2020 13:35:51
User entered 'Yes (Y)'	System	30 Sep 2020 13:35:51

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T09:35:38', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'd3d61d90-20c1-4272-b032-3d5c452b5158' User entered '97.4'	(b) (4), (b) (6) System	30 Sep 2020 13:35:51
	System	30 Sep 2020 13:35:51

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T09:35:41', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'd3d61d90-20c1-4272-b032-3d5c452b5158'	(b) (4), (b) (6)	
System		30 Sep 2020 13:35:51
User entered 'No (N)'	System	30 Sep 2020 13:35:51

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T09:35:44', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'd3d61d90-20c1-4272-b032-3d5c452b5158' User entered '30 Sep 2020 09:35'	(b) (4), (b) (6) System	30 Sep 2020 13:35:51
	System	30 Sep 2020 13:35:51

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:57:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 7'	System	24 Sep 2020 20:46:19



US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T12:00:55', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '67e7c5bd-9f62-4417-939a-c6d2c02dd203' User entered 'Yes (Y)'	System	30 Sep 2020 16:01:45
	System	30 Sep 2020 16:01:45

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T12:01:04', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '67e7c5bd-9f62-4417-939a-c6d2c02dd203' User entered '97.4'	System	30 Sep 2020 16:01:45
	System	30 Sep 2020 16:01:45

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T12:01:06', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '67e7c5bd-9f62-4417-939a-c6d2c02dd203'	(b) (4), (b) (6)	
	System	30 Sep 2020 16:01:45
User entered 'No (N)'	System	30 Sep 2020 16:01:45

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T12:01:09', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '67e7c5bd-9f62-4417-939a-c6d2c02dd203' User entered '30 Sep 2020 12:01'	System	30 Sep 2020 16:01:45
	System	30 Sep 2020 16:01:45

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:57:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-24T17:11:55', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '1e676507-fd42-4a40-a84a-681911774ab3' User entered 'None (1)'	System	24 Sep 2020 21:12:26
	System	24 Sep 2020 21:12:26



US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-24T17:11:59', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '1e676507-fd42-4a40-a84a-681911774ab3'	(b) (4), (b) (6)	
	System	24 Sep 2020 21:12:26
User entered 'No (N)'	System	24 Sep 2020 21:12:26

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-24T17:12:05', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '1e676507-fd42-4a40-a84a-681911774ab3' User entered 'No (N)'	System	24 Sep 2020 21:12:26
	System	24 Sep 2020 21:12:26

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-24T17:12:14', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '1e676507-fd42-4a40-a84a-681911774ab3'	(b) (4), (b) (6)	
	System	24 Sep 2020 21:12:26
User entered 'None (1)'	System	24 Sep 2020 21:12:26

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-24T17:12:20', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '1e676507-fd42-4a40-a84a-681911774ab3'	(b) (4), (b) (6)	
	System	24 Sep 2020 21:12:26
User entered '24 Sep 2020 17:12'	System	24 Sep 2020 21:12:26

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '24 Sep 2020 16:58'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '24 Sep 2020 19:28'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-25T08:20:45', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '5bab72fe-bc89-4f70-a41e-a602292382bd' User entered 'None (1)'	System	25 Sep 2020 12:21:22
	System	25 Sep 2020 12:21:22



US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-25T08:20:48', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '5bab72fe-bc89-4f70-a41e-a602292382bd' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 12:21:22
	System	25 Sep 2020 12:21:22

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-25T08:20:51', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '5bab72fe-bc89-4f70-a41e-a602292382bd' User entered 'No (N)'	System	25 Sep 2020 12:21:22
	System	25 Sep 2020 12:21:22

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-25T08:21:01', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '5bab72fe-bc89-4f70-a41e-a602292382bd' User entered 'None (1)'	(b) (4), (b) (6) System	25 Sep 2020 12:21:22
	System	25 Sep 2020 12:21:22

**US3022233**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-25T08:21:05', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '5bab72fe-bc89-4f70-a41e-a602292382bd' User entered '25 Sep 2020 08:21'	(b) (4), (b) (6) System	25 Sep 2020 12:21:22
	System	25 Sep 2020 12:21:22

**US3022233**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '24 Sep 2020 20:23'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

**US3022233**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '25 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 2'	System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T00:01:36', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b9e6fab9-38dd-4241-85ba-9a4d1218c6f9'	(b) (4), (b) (6) System	26 Sep 2020 04:02:39
User entered 'None (1)'	System	26 Sep 2020 04:02:39



US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T00:01:40', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b9e6fab9-38dd-4241-85ba-9a4d1218c6f9' User entered 'No (N)'	System	26 Sep 2020 04:02:39
	System	26 Sep 2020 04:02:39

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T00:01:43', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b9e6fab9-38dd-4241-85ba-9a4d1218c6f9' User entered 'No (N)'	System	26 Sep 2020 04:02:39
	System	26 Sep 2020 04:02:39

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T00:01:51', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b9e6fab9-38dd-4241-85ba-9a4d1218c6f9'	(b) (4), (b) (6)	
	System	26 Sep 2020 04:02:39
User entered 'None (1)'	System	26 Sep 2020 04:02:39

**US3022233**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T00:01:54', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b9e6fab9-38dd-4241-85ba-9a4d1218c6f9' User entered '26 Sep 2020 00:01'	System	26 Sep 2020 04:02:39
	System	26 Sep 2020 04:02:39

**US3022233**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '25 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

**US3022233**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 3'	System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T14:02:13', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '67d2a54b-ba9e-4c8d-b9b2-01ee83478889' User entered 'None (1)'	System	26 Sep 2020 18:02:28
	System	26 Sep 2020 18:02:28



US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T14:02:16', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '67d2a54b-ba9e-4c8d-b9b2-01ee83478889' User entered 'No (N)'	System	26 Sep 2020 18:02:28
	System	26 Sep 2020 18:02:28

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T14:02:18', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '67d2a54b-ba9e-4c8d-b9b2-01ee83478889' User entered 'No (N)'	System	26 Sep 2020 18:02:28
	System	26 Sep 2020 18:02:28

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T14:02:21', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '67d2a54b-ba9e-4c8d-b9b2-01ee83478889' User entered 'None (1)'	(b) (4), (b) (6) System	26 Sep 2020 18:02:28
	System	26 Sep 2020 18:02:28

**US3022233**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T14:02:25', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '67d2a54b-ba9e-4c8d-b9b2-01ee83478889' User entered '26 Sep 2020 14:02'	System	26 Sep 2020 18:02:28
	System	26 Sep 2020 18:02:28

**US3022233**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:57:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 4'	System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-28T06:14:50', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'd9c6d5d1-4647-4b16-b8b1-eaf9de596ad8'	(b) (4), (b) (6) System	28 Sep 2020 10:15:06
User entered 'None (1)'	System	28 Sep 2020 10:15:06



US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-28T06:14:54', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'd9c6d5d1-4647-4b16-b8b1-eaf9de596ad8' User entered 'No (N)'	System	28 Sep 2020 10:15:06
	System	28 Sep 2020 10:15:06

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-28T06:14:56', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'd9c6d5d1-4647-4b16-b8b1-eaf9de596ad8' User entered 'No (N)'	System	28 Sep 2020 10:15:06
	System	28 Sep 2020 10:15:06

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-28T06:14:58', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'd9c6d5d1-4647-4b16-b8b1-eaf9de596ad8'	(b) (4), (b) (6)	
	System	28 Sep 2020 10:15:06
User entered 'None (1)'	System	28 Sep 2020 10:15:06

**US3022233**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-28T06:15:01', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'd9c6d5d1-4647-4b16-b8b1-eaf9de596ad8' User entered '28 Sep 2020 06:15'	System	28 Sep 2020 10:15:06
	System	28 Sep 2020 10:15:06

**US3022233**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:57:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 5'	System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-29T09:01:46', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'f92240f7-4de0-48d4-bfed-7ead54778296'	(b) (4), (b) (6)	
	System	29 Sep 2020 13:01:59
User entered 'None (1)'	System	29 Sep 2020 13:01:59



US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-29T09:01:49', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'f92240f7-4de0-48d4-bfed-7ead54778296'	(b) (4), (b) (6)	
	System	29 Sep 2020 13:01:59
User entered 'No (N)'	System	29 Sep 2020 13:01:59

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-29T09:01:52', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'f92240f7-4de0-48d4-bfed-7ead54778296'	(b) (4), (b) (6)	
	System	29 Sep 2020 13:01:59
User entered 'No (N)'	System	29 Sep 2020 13:01:59

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-29T09:01:53', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'f92240f7-4de0-48d4-bfed-7ead54778296'	(b) (4), (b) (6)	
	System	29 Sep 2020 13:01:59
User entered 'None (1)'	System	29 Sep 2020 13:01:59

**US3022233**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-29T09:01:56', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'f92240f7-4de0-48d4-bfed-7ead54778296' User entered '29 Sep 2020 09:01'	System	29 Sep 2020 13:01:59
	System	29 Sep 2020 13:01:59

**US3022233**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

**US3022233**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 6'	System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T09:35:47', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fcde301c-4cb4-4727-88e4-54081cd52baf' User entered 'None (1)'	System	30 Sep 2020 13:36:01
	System	30 Sep 2020 13:36:01



US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T09:35:52', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fcde301c-4cb4-4727-88e4-54081cd52baf'	System	30 Sep 2020 13:36:01
User entered 'No (N)'	System	30 Sep 2020 13:36:01

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T09:35:54', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fcde301c-4cb4-4727-88e4-54081cd52baf' User entered 'No (N)'	System	30 Sep 2020 13:36:01
	System	30 Sep 2020 13:36:01

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T09:35:56', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fcde301c-4cb4-4727-88e4-54081cd52baf' User entered 'None (1)'	System	30 Sep 2020 13:36:01
	System	30 Sep 2020 13:36:01

**US3022233**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T09:35:58', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fcde301c-4cb4-4727-88e4-54081cd52baf' User entered '30 Sep 2020 09:35'	(b) (4), (b) (6) System	30 Sep 2020 13:36:01
	System	30 Sep 2020 13:36:01

**US3022233**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

**US3022233**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 7'	System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T12:01:12', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '665775f6-fcda-464c-9254-df31f128d8e1' User entered 'None (1)'	(b) (4), (b) (6) System	30 Sep 2020 16:02:00
	System	30 Sep 2020 16:02:00



US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T12:01:14', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '665775f6-fcda-464c-9254-df31f128d8e1' User entered 'No (N)'	System	30 Sep 2020 16:02:00
	System	30 Sep 2020 16:02:00

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T12:01:17', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '665775f6-fcda-464c-9254-df31f128d8e1' User entered 'No (N)'	System	30 Sep 2020 16:02:00
	System	30 Sep 2020 16:02:00

US3022233

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:57:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T12:01:18', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '665775f6-fcda-464c-9254-df31f128d8e1' User entered 'None (1)'	(b) (4), (b) (6) System	30 Sep 2020 16:02:00
	System	30 Sep 2020 16:02:00

**US3022233**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T12:01:21', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '665775f6-fcda-464c-9254-df31f128d8e1' User entered '30 Sep 2020 12:01'	(b) (4), (b) (6) System	30 Sep 2020 16:02:00
	System	30 Sep 2020 16:02:00

**US3022233**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

**US3022233**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-24T17:12:24', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '433a6a5c-a339-4899-be7f-e0341206b6aa' User entered 'None (0)'	System	24 Sep 2020 21:13:16
	System	24 Sep 2020 21:13:16



US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-24T17:12:27', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '433a6a5c-a339-4899-be7f-e0341206b6aa' User entered 'None (0)'	System	24 Sep 2020 21:13:16
	System	24 Sep 2020 21:13:16

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-24T17:12:30', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '433a6a5c-a339-4899-be7f-e0341206b6aa' User entered 'None (0)'	System	24 Sep 2020 21:13:16
	System	24 Sep 2020 21:13:16

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-24T17:12:34', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '433a6a5c-a339-4899-be7f-e0341206b6aa' User entered 'None (0)'	System	24 Sep 2020 21:13:16
	System	24 Sep 2020 21:13:16

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-24T17:12:36', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '433a6a5c-a339-4899-be7f-e0341206b6aa' User entered 'None (0)'	System	24 Sep 2020 21:13:16
	System	24 Sep 2020 21:13:16

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-24T17:12:38', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '433a6a5c-a339-4899-be7f-e0341206b6aa' User entered 'None (0)'	System	24 Sep 2020 21:13:16
	System	24 Sep 2020 21:13:16

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:57:09

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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-24T17:12:42', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '433a6a5c-a339-4899-be7f-e0341206b6aa' User entered 'No (N)'	System	24 Sep 2020 21:13:16
	System	24 Sep 2020 21:13:16

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-24T17:12:55', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '433a6a5c-a339-4899-be7f-e0341206b6aa' User entered '24 Sep 2020 17:12'	(b) (4), (b) (6) System	24 Sep 2020 21:13:16
	System	24 Sep 2020 21:13:16

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '24 Sep 2020 16:58'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19



**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '24 Sep 2020 19:28'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 20:46:19

**US3022233**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:09**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-25T08:21:09', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fcd50c82-e19f-44e0-bd29-776a0b62bb2a' User entered 'None (0)'	System	25 Sep 2020 12:21:30
	System	25 Sep 2020 12:21:30

**US3022233**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:09**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-25T08:21:13', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fcd50c82-e19f-44e0-bd29-776a0b62bb2a' User entered 'None (0)'	System	25 Sep 2020 12:21:30
	System	25 Sep 2020 12:21:30

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-25T08:21:15', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fcd50c82-e19f-44e0-bd29-776a0b62bb2a' User entered 'None (0)'	System	25 Sep 2020 12:21:30
	System	25 Sep 2020 12:21:30

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-25T08:21:17', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fcd50c82-e19f-44e0-bd29-776a0b62bb2a' User entered 'None (0)'	System	25 Sep 2020 12:21:30
	System	25 Sep 2020 12:21:30

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-25T08:21:19', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fcd50c82-e19f-44e0-bd29-776a0b62bb2a' User entered 'None (0)'	System	25 Sep 2020 12:21:30
	System	25 Sep 2020 12:21:30

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-25T08:21:21', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fcd50c82-e19f-44e0-bd29-776a0b62bb2a' User entered 'None (0)'	System	25 Sep 2020 12:21:30
	System	25 Sep 2020 12:21:30



US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:57:09

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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-25T08:21:24', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fcd50c82-e19f-44e0-bd29-776a0b62bb2a' User entered 'No (N)'	System	25 Sep 2020 12:21:30
	System	25 Sep 2020 12:21:30

**US3022233**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-25T08:21:27', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fcd50c82-e19f-44e0-bd29-776a0b62bb2a' User entered '25 Sep 2020 08:21'	System	25 Sep 2020 12:21:30
	System	25 Sep 2020 12:21:30

**US3022233**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '24 Sep 2020 20:23'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

**US3022233**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '25 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 2'	System	24 Sep 2020 20:46:19

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T00:01:57', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '0a7665fc-cde5-4b9f-b84f-dd223c4a59b5' User entered 'None (0)'	System	26 Sep 2020 04:02:45
	System	26 Sep 2020 04:02:45

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T00:01:59', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '0a7665fc-cde5-4b9f-b84f-dd223c4a59b5' User entered 'None (0)'	System	26 Sep 2020 04:02:45
	System	26 Sep 2020 04:02:45

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T00:02:01', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '0a7665fc-cde5-4b9f-b84f-dd223c4a59b5' User entered 'None (0)'	System	26 Sep 2020 04:02:45
	System	26 Sep 2020 04:02:45



US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T00:02:02', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '0a7665fc-cde5-4b9f-b84f-dd223c4a59b5' User entered 'None (0)'	System	26 Sep 2020 04:02:45
	System	26 Sep 2020 04:02:45

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T00:02:04', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '0a7665fc-cde5-4b9f-b84f-dd223c4a59b5' User entered 'None (0)'	System	26 Sep 2020 04:02:45
	System	26 Sep 2020 04:02:45

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T00:02:06', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '0a7665fc-cde5-4b9f-b84f-dd223c4a59b5' User entered 'None (0)'	System	26 Sep 2020 04:02:45
	System	26 Sep 2020 04:02:45

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:57:09

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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T00:02:09', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '0a7665fc-cde5-4b9f-b84f-dd223c4a59b5' User entered 'No (N)'	System	26 Sep 2020 04:02:45
	System	26 Sep 2020 04:02:45

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T00:02:12', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '0a7665fc-cde5-4b9f-b84f-dd223c4a59b5' User entered '26 Sep 2020 00:02'	(b) (4), (b) (6) System	26 Sep 2020 04:02:45
	System	26 Sep 2020 04:02:45

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '25 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 3'	System	24 Sep 2020 20:46:19



**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T14:02:32', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a85433d8-e94f-491d-8e15-67ee9f47d708' User entered 'None (0)'	System	26 Sep 2020 18:02:52
	System	26 Sep 2020 18:02:52

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T14:02:35', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a85433d8-e94f-491d-8e15-67ee9f47d708' User entered 'None (0)'	System	26 Sep 2020 18:02:52
	System	26 Sep 2020 18:02:52

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T14:02:37', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a85433d8-e94f-491d-8e15-67ee9f47d708' User entered 'None (0)'	System	26 Sep 2020 18:02:52
	System	26 Sep 2020 18:02:52

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T14:02:40', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a85433d8-e94f-491d-8e15-67ee9f47d708' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 18:02:52
	System	26 Sep 2020 18:02:52

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T14:02:42', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a85433d8-e94f-491d-8e15-67ee9f47d708'	(b) (4), (b) (6)	
	System	26 Sep 2020 18:02:52
User entered 'None (0)'	System	26 Sep 2020 18:02:52

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T14:02:45', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a85433d8-e94f-491d-8e15-67ee9f47d708' User entered 'None (0)'	System	26 Sep 2020 18:02:52
	System	26 Sep 2020 18:02:52

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:57:09

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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T14:02:47', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a85433d8-e94f-491d-8e15-67ee9f47d708'	(b) (4), (b) (6)	
	System	26 Sep 2020 18:02:52
User entered 'No (N)'	System	26 Sep 2020 18:02:52

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-26T14:02:50', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a85433d8-e94f-491d-8e15-67ee9f47d708' User entered '26 Sep 2020 14:02'	(b) (4), (b) (6) System	26 Sep 2020 18:02:52
	System	26 Sep 2020 18:02:52



**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 4'	System	24 Sep 2020 20:46:19

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-28T06:15:05', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'dc9be264-0657-4752-a8f6-6e0dccefe98f' User entered 'None (0)'	System	28 Sep 2020 10:15:24
	System	28 Sep 2020 10:15:24

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-28T06:15:07', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'dc9be264-0657-4752-a8f6-6e0dccefe98f' User entered 'None (0)'	System	28 Sep 2020 10:15:24
	System	28 Sep 2020 10:15:24

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-28T06:15:09', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'dc9be264-0657-4752-a8f6-6e0dccefe98f' User entered 'None (0)'	System	28 Sep 2020 10:15:24
	System	28 Sep 2020 10:15:24

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-28T06:15:10', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'dc9be264-0657-4752-a8f6-6e0dccefe98f' User entered 'None (0)'	System	28 Sep 2020 10:15:24
	System	28 Sep 2020 10:15:24

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-28T06:15:12', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'dc9be264-0657-4752-a8f6-6e0dccefe98f' User entered 'None (0)'	System	28 Sep 2020 10:15:24
	System	28 Sep 2020 10:15:24



**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-28T06:15:14', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'dc9be264-0657-4752-a8f6-6e0dccefe98f' User entered 'None (0)'	System	28 Sep 2020 10:15:24
	System	28 Sep 2020 10:15:24

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:57:09

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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-28T06:15:17', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'dc9be264-0657-4752-a8f6-6e0dccefe98f' User entered 'No (N)'	System	28 Sep 2020 10:15:24
	System	28 Sep 2020 10:15:24

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-28T06:15:19', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'dc9be264-0657-4752-a8f6-6e0dccefe98f' User entered '28 Sep 2020 06:15'	System	28 Sep 2020 10:15:24
	System	28 Sep 2020 10:15:24

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 5'	System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-29T09:02:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '45816913-8448-4a1c-9f47-e04c840ce43d' User entered 'None (0)'	System	29 Sep 2020 13:02:16
	System	29 Sep 2020 13:02:16

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-29T09:02:02', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '45816913-8448-4a1c-9f47-e04c840ce43d' User entered 'None (0)'	System	29 Sep 2020 13:02:16
	System	29 Sep 2020 13:02:16



US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-29T09:02:03', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '45816913-8448-4a1c-9f47-e04c840ce43d' User entered 'None (0)'	System	29 Sep 2020 13:02:16
	System	29 Sep 2020 13:02:16

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-29T09:02:05', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '45816913-8448-4a1c-9f47-e04c840ce43d' User entered 'None (0)'	System	29 Sep 2020 13:02:16
	System	29 Sep 2020 13:02:16

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-29T09:02:06', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '45816913-8448-4a1c-9f47-e04c840ce43d' User entered 'None (0)'	System	29 Sep 2020 13:02:16
	System	29 Sep 2020 13:02:16

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-29T09:02:08', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '45816913-8448-4a1c-9f47-e04c840ce43d' User entered 'None (0)'	System	29 Sep 2020 13:02:16
	System	29 Sep 2020 13:02:16

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:57:09

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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-29T09:02:12', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '45816913-8448-4a1c-9f47-e04c840ce43d' User entered 'No (N)'	System	29 Sep 2020 13:02:16
	System	29 Sep 2020 13:02:16

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-29T09:02:14', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '45816913-8448-4a1c-9f47-e04c840ce43d' User entered '29 Sep 2020 09:02'	(b) (4), (b) (6) System	29 Sep 2020 13:02:16
	System	29 Sep 2020 13:02:16

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19



US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 6'	System	24 Sep 2020 20:46:19

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T09:36:01', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '4c2ecb19-8ee4-43d5-bd0c-73f0a3dc8b53' User entered 'None (0)'	System	30 Sep 2020 13:36:16
	System	30 Sep 2020 13:36:16

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T09:36:03', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '4c2ecb19-8ee4-43d5-bd0c-73f0a3dc8b53' User entered 'None (0)'	System	30 Sep 2020 13:36:16
	System	30 Sep 2020 13:36:16

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T09:36:04', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '4c2ecb19-8ee4-43d5-bd0c-73f0a3dc8b53' User entered 'None (0)'	System	30 Sep 2020 13:36:16
	System	30 Sep 2020 13:36:16

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T09:36:06', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '4c2ecb19-8ee4-43d5-bd0c-73f0a3dc8b53' User entered 'None (0)'	System	30 Sep 2020 13:36:16
	System	30 Sep 2020 13:36:16

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T09:36:08', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '4c2ecb19-8ee4-43d5-bd0c-73f0a3dc8b53' User entered 'None (0)'	System	30 Sep 2020 13:36:16
	System	30 Sep 2020 13:36:16

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T09:36:09', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '4c2ecb19-8ee4-43d5-bd0c-73f0a3dc8b53' User entered 'None (0)'	System	30 Sep 2020 13:36:16
	System	30 Sep 2020 13:36:16

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:57:09

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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T09:36:12', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '4c2ecb19-8ee4-43d5-bd0c-73f0a3dc8b53'	(b) (4), (b) (6)	
	System	30 Sep 2020 13:36:16
User entered 'No (N)'	System	30 Sep 2020 13:36:16



**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T09:36:14', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '4c2ecb19-8ee4-43d5-bd0c-73f0a3dc8b53' User entered '30 Sep 2020 09:36'	(b) (4), (b) (6) System	30 Sep 2020 13:36:16
	System	30 Sep 2020 13:36:16

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	24 Sep 2020 20:46:19
User entered 'Day 7'	System	24 Sep 2020 20:46:19

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T12:01:24', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '9f7d1365-4eca-4c2c-9b3c-602d74d8bee0' User entered 'None (0)'	System	30 Sep 2020 16:02:25
	System	30 Sep 2020 16:02:25

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T12:01:25', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '9f7d1365-4eca-4c2c-9b3c-602d74d8bee0' User entered 'None (0)'	System	30 Sep 2020 16:02:25
	System	30 Sep 2020 16:02:25

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T12:01:27', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '9f7d1365-4eca-4c2c-9b3c-602d74d8bee0' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 16:02:25
	System	30 Sep 2020 16:02:25

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T12:01:28', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '9f7d1365-4eca-4c2c-9b3c-602d74d8bee0' User entered 'None (0)'	System	30 Sep 2020 16:02:25
	System	30 Sep 2020 16:02:25



US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T12:01:30', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '9f7d1365-4eca-4c2c-9b3c-602d74d8bee0' User entered 'None (0)'	System	30 Sep 2020 16:02:25
	System	30 Sep 2020 16:02:25

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T12:01:31', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '9f7d1365-4eca-4c2c-9b3c-602d74d8bee0' User entered 'None (0)'	System	30 Sep 2020 16:02:25
	System	30 Sep 2020 16:02:25

US3022233

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:57:09

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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T12:01:34', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '9f7d1365-4eca-4c2c-9b3c-602d74d8bee0' User entered 'No (N)'	System	30 Sep 2020 16:02:25
	System	30 Sep 2020 16:02:25

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-09-30T12:01:36', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '9f7d1365-4eca-4c2c-9b3c-602d74d8bee0' User entered '30 Sep 2020 12:01'	(b) (4), (b) (6) System	30 Sep 2020 16:02:25
	System	30 Sep 2020 16:02:25

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

**US3022233**

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

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

**Generated On: 11 Aug 2021 21:57:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 20:46:19

**US3022233**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 18:34:18

**US3022233**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '01 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 18:34:18



US3022233

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Oct 2020 18:34:18

**US3022233**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:34:18

US3022233

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 18:34:22

**US3022233**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered '1'	(b) (4), (b) (6) System	01 Oct 2020 18:34:22

**US3022233**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 17:53:28

**US3022233**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '08 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 17:53:28

**US3022233**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Oct 2020 17:53:28

**US3022233**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 17:53:28



US3022233

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 17:54:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Oct 2020 17:54:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 17:54:21
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 17:53:34
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 17:53:34

**US3022233**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered '1'	(b) (4), (b) (6)	08 Oct 2020 17:54:21
User entered empty.	System	08 Oct 2020 17:53:34

**US3022233**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Nov 2020 22:00:19
	(b) (4)	

**US3022233**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	17 Nov 2020 22:00:19
	(b) (4)	

**US3022233**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	17 Nov 2020 22:00:19
	(b) (4)	

US3022233

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:57:09

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	17 Nov 2020 22:00:19
	(b) (4)	

**US3022233**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	17 Nov 2020 22:00:23
	(b) (4)	

**US3022233**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered '1'	(b) (4), (b) (6) System	17 Nov 2020 22:00:23



**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 20:47:21

US3022233

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:57:09

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	04 Dec 2020 12:34:43
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.'	(b) (4), (b) (6)	03 Dec 2020 20:47:31
answered with 'this is correct' (Site from System).		
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	03 Dec 2020 20:47:21
User entered '16 Nov 2020'	(b) (4), (b) (6)	03 Dec 2020 20:47:21

US3022233

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	03 Dec 2020 20:47:21

**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'VISIT3'	(b) (4), (b) (6) System	03 Dec 2020 20:47:21

**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 20:47:55

**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '16 Nov 2020'	(b) (4), (b) (6)	03 Dec 2020 20:47:55

**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '16:26'	(b) (4), (b) (6)	03 Dec 2020 20:47:55

**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered '16 Nov 2020 16:26'	(b) (4), (b) (6) System	03 Dec 2020 20:47:55



**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '36.8' C	(b) (4), (b) (6)	03 Dec 2020 20:47:55

**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:47:55

**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 20:47:55

**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '85'	(b) (4), (b) (6)	03 Dec 2020 20:47:55

US3022233

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'bpm'	(b) (4), (b) (6) System	03 Dec 2020 20:47:55

US3022233

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '16'	(b) (4), (b) (6)	03 Dec 2020 20:47:55

US3022233

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'breaths/min'	(b) (4), (b) (6) System	03 Dec 2020 20:47:55

**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '120'	(b) (4), (b) (6)	03 Dec 2020 20:47:55



**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'mmHg'	(b) (4), (b) (6) System	03 Dec 2020 20:47:55

**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '74'	(b) (4), (b) (6)	03 Dec 2020 20:47:55

US3022233

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'mmHg'	(b) (4), (b) (6) System	03 Dec 2020 20:47:55

**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 19:28:46

**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 19:28:46

US3022233

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 20:48:09

US3022233

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '16 Nov 2020'	(b) (4), (b) (6)	03 Dec 2020 20:48:09

**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 20:48:24



**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:09**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '16 Nov 2020'	(b) (4), (b) (6)	03 Dec 2020 20:48:24

**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '16:34'	(b) (4), (b) (6)	03 Dec 2020 20:48:24

**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered '16 Nov 2020 16:34'	(b) (4), (b) (6) System	03 Dec 2020 20:48:24

**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 20:48:30

**US3022233**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered '1'	(b) (4), (b) (6) System	03 Dec 2020 20:48:30

**US3022233**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 64'	System	20 Aug 2020 22:51:32

US3022233

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

[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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-10-23T13:38:55', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '999e25d4-b47a-4437-a030-39cc745beea9'	(b) (4), (b) (6)	23 Oct 2020 17:39:25
User entered 'No (N)'	System	23 Oct 2020 17:39:25

US3022233

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

Have you been exposed to someone with 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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-10-23T13:39:08', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '999e25d4-b47a-4437-a030-39cc745beea9'	(b) (4), (b) (6)	23 Oct 2020 17:39:25
User entered 'No (N)'	System	23 Oct 2020 17:39:25



**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-10-23T13:39:21', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '999e25d4-b47a-4437-a030-39cc745beea9' User entered '23 Oct 2020 13:39:21'	System	23 Oct 2020 17:39:25
	System	23 Oct 2020 17:39:25

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 22:51:32
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 22:51:32

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 22:51:32
	System	20 Aug 2020 22:51:32

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 71'	System	20 Aug 2020 22:51:32

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-10-27T07:15:58', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'f3ea0e5e-0d40-4f78-81ba-148a86d8c585'	(b) (4), (b) (6)	
	System	27 Oct 2020 11:16:29
User entered 'No (N)'	System	27 Oct 2020 11:16:29

US3022233

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

Have you been exposed to someone with 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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-10-27T07:16:13', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'f3ea0e5e-0d40-4f78-81ba-148a86d8c585'	(b) (4), (b) (6)	
	System	27 Oct 2020 11:16:29
User entered 'No (N)'	System	27 Oct 2020 11:16:29

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-10-27T07:16:24', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'f3ea0e5e-0d40-4f78-81ba-148a86d8c585' User entered '27 Oct 2020 07:16:24'	System	27 Oct 2020 11:16:29
	System	27 Oct 2020 11:16:29

US3022233

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 22:51:32



**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 22:51:32
	System	20 Aug 2020 22:51:32

US3022233

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 78'	System	20 Aug 2020 22:51:32

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

US3022233

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

[Have you been exposed to someone with 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)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

US3022233

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11



US3022233

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11
Data entry locked.	System	20 Aug 2020 22:51:32
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 22:51:32

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:16:11
Data entry locked.	System	20 Aug 2020 22:51:32
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 22:51:32

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 22:51:32
User entered 'Day 92'	System	20 Aug 2020 22:51:32

US3022233

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

[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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-11-17T05:34:06', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '311485cc-9071-42a4-bd59-b40d5c19c4bd' User entered 'No (N)'	(b) (4), (b) (6) System	17 Nov 2020 10:34:24
	System	17 Nov 2020 10:34:24

US3022233

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:57:09

Have you been exposed to someone with 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)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-11-17T05:34:14', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '311485cc-9071-42a4-bd59-b40d5c19c4bd'	(b) (4), (b) (6)	
User entered 'No (N)'	System	17 Nov 2020 10:34:24



**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-11-17T05:34:20', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '311485cc-9071-42a4-bd59-b40d5c19c4bd' User entered '17 Nov 2020 05:34:20'	System	17 Nov 2020 10:34:24
	System	17 Nov 2020 10:34:24

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 22:51:32
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 22:51:32

**US3022233**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:10:38
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 22:51:32
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 22:51:32

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-11-23T04:46:07', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '3254f872-9b80-4756-bfb5-a5e3893d8bdc' User entered 'No (N)'	System	23 Nov 2020 09:53:48
	System	23 Nov 2020 09:53:48

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Have you been exposed to someone with 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 (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-11-23T04:46:12', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '3254f872-9b80-4756-bfb5-a5e3893d8bdc' User entered 'No (N)'	System	23 Nov 2020 09:53:48

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-11-23T04:46:20', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '3254f872-9b80-4756-bfb5-a5e3893d8bdc' User entered '23 Nov 2020 04:46:20'	System	23 Nov 2020 09:53:48
	System	23 Nov 2020 09:53:48

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-11-29T14:06:53', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '19632b3f-bfcd-49d2-bfff-483d4fc48ed8'	System	29 Nov 2020 19:07:08
User entered 'No (N)'	System	29 Nov 2020 19:07:08

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Have you been exposed to someone with 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 (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-11-29T14:06:58', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '19632b3f-bfcd-49d2-bfff-483d4fc48ed8'	System	29 Nov 2020 19:07:08
User entered 'No (N)'	System	29 Nov 2020 19:07:08

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-11-29T14:07:04', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '19632b3f-bfcd-49d2-bfff-483d4fc48ed8'	System	29 Nov 2020 19:07:08
User entered '29 Nov 2020 14:07:04'	System	29 Nov 2020 19:07:08

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-12-07T08:15:28', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '7def13ab-42ed-460d-b154-697ee7d8707c' User entered 'No (N)'	System	07 Dec 2020 13:16:01
	System	07 Dec 2020 13:16:01

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Have you been exposed to someone with 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 (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-12-07T08:15:35', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '7def13ab-42ed-460d-b154-697ee7d8707c' User entered 'Yes (Y)'	System	07 Dec 2020 13:16:01
	System	07 Dec 2020 13:16:01

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-12-07T08:15:43', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '7def13ab-42ed-460d-b154-697ee7d8707c'	System	07 Dec 2020 13:16:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Dec 2020 13:16:01

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-12-07T08:15:51', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '7def13ab-42ed-460d-b154-697ee7d8707c' User entered '07 Dec 2020 08:15:51'	System	07 Dec 2020 13:16:01
	System	07 Dec 2020 13:16:01

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-12-12T12:25:49', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '783b5981-a2b9-4528-9e59-6e8cdb3c25a2' User entered 'No (N)'	System	12 Dec 2020 17:26:09
	System	12 Dec 2020 17:26:09



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Have you been exposed to someone with 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 (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-12-12T12:26:02', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '783b5981-a2b9-4528-9e59-6e8cdb3c25a2'	System	12 Dec 2020 17:26:09
User entered 'No (N)'	System	12 Dec 2020 17:26:09

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-12-12T12:26:07', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '783b5981-a2b9-4528-9e59-6e8cdb3c25a2'	System	12 Dec 2020 17:26:09
User entered '12 Dec 2020 12:26:07'	System	12 Dec 2020 17:26:09

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-12-21T12:44:09', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a4caee89-6de8-431b-aaaf-1cf505fc1f01'	System	21 Dec 2020 17:44:24
User entered 'No (N)'	System	21 Dec 2020 17:44:24

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Have you been exposed to someone with 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 (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-12-21T12:44:15', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a4caee89-6de8-431b-aaaf-1cf505fc1f01'	System	21 Dec 2020 17:44:24
User entered 'No (N)'	System	21 Dec 2020 17:44:24

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-12-21T12:44:21', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a4caee89-6de8-431b-aaaf-1cf505fc1f01' User entered '21 Dec 2020 12:44:21'	System	21 Dec 2020 17:44:24



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-12-26T07:16:08', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '53ddbbe8-a36c-4d83-8693-52c17fd245ce' User entered 'No (N)'	System	26 Dec 2020 12:16:20
	System	26 Dec 2020 12:16:20

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Have you been exposed to someone with 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 (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-12-26T07:16:13', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '53ddbbe8-a36c-4d83-8693-52c17fd245ce' User entered 'No (N)'	System	26 Dec 2020 12:16:20
	System	26 Dec 2020 12:16:20

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2020-12-26T07:16:18', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '53ddbbe8-a36c-4d83-8693-52c17fd245ce' User entered '26 Dec 2020 07:16:18'	System	26 Dec 2020 12:16:20
	System	26 Dec 2020 12:16:20

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2021-01-02T00:22:06', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '67d65356-256a-462f-bc7b-886ad5326377'	System	02 Jan 2021 05:22:30
User entered 'No (N)'	System	02 Jan 2021 05:22:30

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Have you been exposed to someone with 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 (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2021-01-02T00:22:09', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '67d65356-256a-462f-bc7b-886ad5326377'	System	02 Jan 2021 05:22:30
User entered 'No (N)'	System	02 Jan 2021 05:22:30

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2021-01-02T00:22:12', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '67d65356-256a-462f-bc7b-886ad5326377'	System	02 Jan 2021 05:22:30
User entered '02 Jan 2021 00:22:12'	System	02 Jan 2021 05:22:30

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2021-01-09T07:45:42', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '718e0f2b-de98-4aac-8515-1f569596fae0' User entered 'No (N)'	System	09 Jan 2021 12:45:49
	System	09 Jan 2021 12:45:49



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Have you been exposed to someone with 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 (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2021-01-09T07:45:45', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '718e0f2b-de98-4aac-8515-1f569596fae0' User entered 'No (N)'	System	09 Jan 2021 12:45:49
	System	09 Jan 2021 12:45:49

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2021-01-09T07:45:47', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '718e0f2b-de98-4aac-8515-1f569596fae0' User entered '09 Jan 2021 07:45:47'	System	09 Jan 2021 12:45:49
	System	09 Jan 2021 12:45:49

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2021-01-18T12:00:47', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'dc4b4c71-4f6c-481c-9237-8bb2251be618' User entered 'No (N)'	System	18 Jan 2021 17:01:44
	System	18 Jan 2021 17:01:44

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Have you been exposed to someone with 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 (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2021-01-18T12:00:54', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'dc4b4c71-4f6c-481c-9237-8bb2251be618' User entered 'No (N)'	System	18 Jan 2021 17:01:44

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2021-01-18T12:00:56', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'dc4b4c71-4f6c-481c-9237-8bb2251be618' User entered '18 Jan 2021 12:00:56'	System	18 Jan 2021 17:01:44



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2021-01-25T19:06:24', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b0a98bf6-5f30-47df-bf57-0cc8b392383c' User entered 'No (N)'	System	26 Jan 2021 00:06:46

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Have you been exposed to someone with 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 (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2021-01-25T19:06:38', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b0a98bf6-5f30-47df-bf57-0cc8b392383c' User entered 'No (N)'	System	26 Jan 2021 00:06:46

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D69F7BA3-CFC3-4B90-9C92-E72313CEB6AF)', Time: '2021-01-25T19:06:43', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b0a98bf6-5f30-47df-bf57-0cc8b392383c' User entered '25 Jan 2021 19:06:43'	System	26 Jan 2021 00:06:46

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (bfce8cd3a23d46c4)', Time: '2021-02-02T11:14:10', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '03e97260-d396-4bb3-a5c5-c5edd2f4772e'	System	02 Feb 2021 16:14:21
User entered 'No (N)'	System	02 Feb 2021 16:14:21

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Have you been exposed to someone with 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 (bfce8cd3a23d46c4)', Time: '2021-02-02T11:14:15', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '03e97260-d396-4bb3-a5c5-c5edd2f4772e'	System	02 Feb 2021 16:14:21
User entered 'No (N)'	System	02 Feb 2021 16:14:21

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfce8cd3a23d46c4)', Time: '2021-02-02T11:14:19', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '03e97260-d396-4bb3-a5c5-c5edd2f4772e' User entered '02 Feb 2021 11:14:19'	System	02 Feb 2021 16:14:21
	System	02 Feb 2021 16:14:21

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (bfce8cd3a23d46c4)', Time: '2021-02-06T09:34:48', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '5087dc09-3b6c-4a80-b2db-5810aad7cb03'	System	06 Feb 2021 14:34:58
User entered 'No (N)'	System	06 Feb 2021 14:34:58



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Have you been exposed to someone with 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 (bfce8cd3a23d46c4)', Time: '2021-02-06T09:34:52', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '5087dc09-3b6c-4a80-b2db-5810aad7cb03'	System	06 Feb 2021 14:34:58
User entered 'No (N)'	System	06 Feb 2021 14:34:58

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfce8cd3a23d46c4)', Time: '2021-02-06T09:34:55', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '5087dc09-3b6c-4a80-b2db-5810aad7cb03'	System	06 Feb 2021 14:34:58
User entered '06 Feb 2021 09:34:55'	System	06 Feb 2021 14:34:58

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (bfce8cd3a23d46c4)', Time: '2021-02-13T00:24:43', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '4d6fe485-3372-4774-8e0a-a08b0ff0044d'	System	13 Feb 2021 05:25:06
User entered 'No (N)'	System	13 Feb 2021 05:25:06

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Have you been exposed to someone with 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 (bfce8cd3a23d46c4)', Time: '2021-02-13T00:24:47', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '4d6fe485-3372-4774-8e0a-a08b0ff0044d'	System	13 Feb 2021 05:25:06
User entered 'No (N)'	System	13 Feb 2021 05:25:06

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfce8cd3a23d46c4)', Time: '2021-02-13T00:24:50', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '4d6fe485-3372-4774-8e0a-a08b0ff0044d'	System	13 Feb 2021 05:25:06
User entered '13 Feb 2021 00:24:50'	System	13 Feb 2021 05:25:06



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (bfce8cd3a23d46c4)', Time: '2021-02-22T17:23:57', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '3f06e0a0-408e-4be4-91b6-d5b3c1a9aea5'	System	22 Feb 2021 22:24:09
User entered 'No (N)'	System	22 Feb 2021 22:24:09

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Have you been exposed to someone with 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 (bfce8cd3a23d46c4)', Time: '2021-02-22T17:24:01', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '3f06e0a0-408e-4be4-91b6-d5b3c1a9aea5'	System	22 Feb 2021 22:24:09
User entered 'No (N)'	System	22 Feb 2021 22:24:09

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfce8cd3a23d46c4)', Time: '2021-02-22T17:24:05', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '3f06e0a0-408e-4be4-91b6-d5b3c1a9aea5'	System	22 Feb 2021 22:24:09
User entered '22 Feb 2021 17:24:05'	System	22 Feb 2021 22:24:09

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (bfce8cd3a23d46c4)', Time: '2021-02-27T04:47:22-05:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '1b2bb71f-9794-45a0-8b9c-70c91b35a1ac' User entered 'Yes (Y)'	System	27 Feb 2021 09:48:04
	System	27 Feb 2021 09:48:04

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Have you been exposed to someone with 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 (bfce8cd3a23d46c4)', Time: '2021-02-27T04:47:27-05:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '1b2bb71f-9794-45a0-8b9c-70c91b35a1ac'	System	27 Feb 2021 09:48:04
User entered 'No (N)'	System	27 Feb 2021 09:48:04

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfce8cd3a23d46c4)', Time: '2021-02-27T04:47:35-05:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '1b2bb71f-9794-45a0-8b9c-70c91b35a1ac'	System	27 Feb 2021 09:48:04
User entered 'No (N)'	System	27 Feb 2021 09:48:04

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfce8cd3a23d46c4)', Time: '2021-02-27T04:47:42-05:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '1b2bb71f-9794-45a0-8b9c-70c91b35a1ac'	System	27 Feb 2021 09:48:04
User entered 'Yes (Y)'	System	27 Feb 2021 09:48:04

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfce8cd3a23d46c4)', Time: '2021-02-27T04:47:53-05:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '1b2bb71f-9794-45a0-8b9c-70c91b35a1ac'	System	27 Feb 2021 09:48:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Feb 2021 09:48:04

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfce8cd3a23d46c4)', Time: '2021-02-27T04:47:59-05:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '1b2bb71f-9794-45a0-8b9c-70c91b35a1ac'	System	27 Feb 2021 09:48:04
User entered '27 Feb 2021 04:47:59'	System	27 Feb 2021 09:48:04

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (bfce8cd3a23d46c4)', Time: '2021-03-09T13:44:36-05:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'aa146f6c-ebd4-4ec9-a023-ce86d358c75f' User entered 'No (N)'	System	09 Mar 2021 18:44:43

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Have you been exposed to someone with 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 (bfce8cd3a23d46c4)', Time: '2021-03-09T13:44:39-05:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'aa146f6c-ebd4-4ec9-a023-ce86d358c75f'	System	09 Mar 2021 18:44:43
User entered 'No (N)'	System	09 Mar 2021 18:44:43

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfce8cd3a23d46c4)', Time: '2021-03-09T13:44:42-05:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'aa146f6c-ebd4-4ec9-a023-ce86d358c75f' User entered '09 Mar 2021 13:44:42'	System	09 Mar 2021 18:44:43
	System	09 Mar 2021 18:44:43

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (bfce8cd3a23d46c4)', Time: '2021-03-13T08:22:57-05:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b77b0af3-80a2-4828-b5f1-fe44ca5ec48a' User entered 'No (N)'	System	13 Mar 2021 13:23:07

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Have you been exposed to someone with 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 (bfce8cd3a23d46c4)', Time: '2021-03-13T08:23:01-05:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b77b0af3-80a2-4828-b5f1-fe44ca5ec48a'	System	13 Mar 2021 13:23:07
User entered 'No (N)'	System	13 Mar 2021 13:23:07

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfce8cd3a23d46c4)', Time: '2021-03-13T08:23:04-05:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'b77b0af3-80a2-4828-b5f1-fe44ca5ec48a' User entered '13 Mar 2021 08:23:04'	System	13 Mar 2021 13:23:07
	System	13 Mar 2021 13:23:07

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (bfce8cd3a23d46c4)', Time: '2021-03-23T21:45:29-04:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '18fafde0-d809-4cb2-bbbd-8080f3527aaa'	System	24 Mar 2021 01:45:40
User entered 'No (N)'	System	24 Mar 2021 01:45:40

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Have you been exposed to someone with 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 (bfce8cd3a23d46c4)', Time: '2021-03-23T21:45:33-04:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '18fafde0-d809-4cb2-bbbd-8080f3527aaa'	System	24 Mar 2021 01:45:40
User entered 'No (N)'	System	24 Mar 2021 01:45:40



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfce8cd3a23d46c4)', Time: '2021-03-23T21:45:36-04:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '18fafde0-d809-4cb2-bbbd-8080f3527aaa'	System	24 Mar 2021 01:45:40
User entered '23 Mar 2021 21:45:36'	System	24 Mar 2021 01:45:40

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (bfce8cd3a23d46c4)', Time: '2021-04-03T05:57:53-04:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '8b672212-a09d-41dd-8646-d9ca2486920e'	System	03 Apr 2021 09:58:14
User entered 'No (N)'	System	03 Apr 2021 09:58:14



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Have you been exposed to someone with 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 (bfce8cd3a23d46c4)', Time: '2021-04-03T05:57:32-04:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '8b672212-a09d-41dd-8646-d9ca2486920e'	System	03 Apr 2021 09:58:14
User entered 'No (N)'	System	03 Apr 2021 09:58:14

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfce8cd3a23d46c4)', Time: '2021-04-03T05:58:09-04:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '8b672212-a09d-41dd-8646-d9ca2486920e'	System	03 Apr 2021 09:58:14
User entered '03 Apr 2021 05:58:09'	System	03 Apr 2021 09:58:14

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (bfce8cd3a23d46c4)', Time: '2021-04-12T19:00:00-04:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a914f6ae-d46d-4d6d-aabb-705cf82a6b2b'	System	12 Apr 2021 23:00:20
User entered 'No (N)'	System	12 Apr 2021 23:00:20

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Have you been exposed to someone with 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 (bfce8cd3a23d46c4)', Time: '2021-04-12T19:00:02-04:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a914f6ae-d46d-4d6d-aabb-705cf82a6b2b'	System	12 Apr 2021 23:00:20
User entered 'No (N)'	System	12 Apr 2021 23:00:20

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfce8cd3a23d46c4)', Time: '2021-04-12T19:00:05-04:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'a914f6ae-d46d-4d6d-aabb-705cf82a6b2b'	System	12 Apr 2021 23:00:20
User entered '12 Apr 2021 19:00:05'	System	12 Apr 2021 23:00:20



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (bfce8cd3a23d46c4)', Time: '2021-04-19T12:00:37-04:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fcabd8a6-f537-4358-9e95-5f3d9362a267'	System	19 Apr 2021 16:03:17
User entered 'No (N)'	System	19 Apr 2021 16:03:17

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Have you been exposed to someone with 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 (bfce8cd3a23d46c4)', Time: '2021-04-19T12:00:45-04:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fcabd8a6-f537-4358-9e95-5f3d9362a267'	System	19 Apr 2021 16:03:17
User entered 'Yes (Y)'	System	19 Apr 2021 16:03:17

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfce8cd3a23d46c4)', Time: '2021-04-19T12:00:57-04:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fcabd8a6-f537-4358-9e95-5f3d9362a267'	System	19 Apr 2021 16:03:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Apr 2021 16:03:17

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfce8cd3a23d46c4)', Time: '2021-04-19T12:01:00-04:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: 'fcabd8a6-f537-4358-9e95-5f3d9362a267'	System	19 Apr 2021 16:03:17
User entered '19 Apr 2021 12:01:00'	System	19 Apr 2021 16:03:17

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[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 (bfce8cd3a23d46c4)', Time: '2021-04-24T20:20:46-04:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '83fcf9ea-34d2-4709-a17a-3bacc2ec196d' User entered 'No (N)'	System	25 Apr 2021 00:20:57

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

Have you been exposed to someone with 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 (bfce8cd3a23d46c4)', Time: '2021-04-24T20:20:51-04:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '83fcf9ea-34d2-4709-a17a-3bacc2ec196d'	System	25 Apr 2021 00:20:57
User entered 'No (N)'	System	25 Apr 2021 00:20:57

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfce8cd3a23d46c4)', Time: '2021-04-24T20:20:53-04:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '83fcf9ea-34d2-4709-a17a-3bacc2ec196d'	System	25 Apr 2021 00:20:57
User entered '24 Apr 2021 20:20:53'	System	25 Apr 2021 00:20:57

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:16:11



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:16:11



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:16:11

**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 00:16:11



**US3022233**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:57:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:16:11
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 00:16:11

US3022233

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 21:57:09**

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)	24 Apr 2021 09:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfce8cd3a23d46c4)', Time: '2021-03-09T13:44:52-05:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '398365aa-0c47-4de6-9c5c-a0f5e4f8c5e2'	(b) (4), (b) (6)	09 Mar 2021 18:45:13
User entered 'No (N)'	System	09 Mar 2021 18:45:13

**US3022233**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:32:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bfce8cd3a23d46c4)', Time: '2021-03-09T13:45:03-05:00', User OID: 'PatientReportedOutcome (US3022233)', ODM File OID: '398365aa-0c47-4de6-9c5c-a0f5e4f8c5e2'	(b) (4), (b) (6)	09 Mar 2021 18:45:13
User entered '09 Mar 2021 13:45:03'	System	09 Mar 2021 18:45:13

**US3022233**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 20:48:46

**US3022233**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered '17 Nov 2020'	(b) (4), (b) (6)	03 Dec 2020 20:48:46

**US3022233**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Dec 2020 20:48:46

**US3022233**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 20:48:46

**US3022233**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 20:48:50



**US3022233**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'I'	(b) (4), (b) (6) System	03 Dec 2020 20:48:50

**US3022233**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:00:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:45:12

**US3022233**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:00:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered '22 Dec 2020'	(b) (4), (b) (6)	20 Jan 2021 20:45:12

**US3022233**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:00:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Jan 2021 20:45:12

**US3022233**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:00:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:45:12

**US3022233**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:00:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 20:45:16

**US3022233**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:00:37
User entered 'I'	System	20 Jan 2021 20:45:16

**US3022233**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:00:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 20:45:35



**US3022233**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:00:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User entered '20 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 20:45:35

**US3022233**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:00:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Jan 2021 20:45:35

**US3022233**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:00:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 20:45:35

**US3022233**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:00:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 20:45:42

**US3022233**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:00:37
User entered '1'	System	20 Jan 2021 20:45:42

**US3022233**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:00:37
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:01:18

**US3022233**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:00:37
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:01:18

**US3022233**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:00:37
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Mar 2021 17:01:18



**US3022233**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:00:37
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:01:18

**US3022233**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:00:37
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:01:27

**US3022233**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:00:37
User entered '1'	System	17 Mar 2021 17:01:27

US3022233

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:57:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User closed query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed .Vital signs if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately.' (Site from DM).		19 Apr 2021 19:45:20
Query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed .Vital signs if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately.' answered with 'updated ' (Site from DM).		09 Apr 2021 18:31:11
User opened query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D29 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed .Vital signs if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately.' (Site from DM).		07 Apr 2021 17:00:22
User closed query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).		07 Apr 2021 17:00:22
Query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' answered with 'not required per protocol ' (Site from DM).		30 Mar 2021 14:38:34

US3022233

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:57:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 04:28:59
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 17:02:49

**US3022233**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '09 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 17:02:49

**US3022233**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 17:02:49

**US3022233**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User entered 'VISIT4'	System	17 Mar 2021 17:02:49



US3022233

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:31:01
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 16:57:06

US3022233

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:07
User entered '09 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:31:01
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:57:06

**US3022233**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:07
User entered '14:23' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:31:01
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:57:06

**US3022233**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User entered '09 Mar 2021 14:23'	System	09 Apr 2021 18:31:01
User entered empty.	System	30 Mar 2021 16:57:06

US3022233

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:07
User entered '36.6' C reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:31:01
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:57:06

US3022233

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:07
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:31:01
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:57:06

**US3022233**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:07
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:57:06

US3022233

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:07
User entered '82' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:31:01
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:57:06



**US3022233**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User entered 'bpm'	System	09 Apr 2021 18:31:01
User entered empty.	System	30 Mar 2021 16:57:06

US3022233

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:07
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:31:01
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:57:06

US3022233

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User entered 'breaths/min'	System	09 Apr 2021 18:31:01
User entered empty.	System	30 Mar 2021 16:57:06

US3022233

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:07
User entered '123' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:31:01
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:57:06

US3022233

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User entered 'mmHg'	System	09 Apr 2021 18:31:01
User entered empty.	System	30 Mar 2021 16:57:06

US3022233

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:07
User entered '74' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:31:01
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:57:06

US3022233

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User entered 'mmHg'	System	09 Apr 2021 18:31:01
User entered empty.	System	30 Mar 2021 16:57:06

**US3022233**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34



US3022233

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34

**US3022233**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:57:09**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 17:03:02

**US3022233**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:57:09**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '09 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 17:03:02

**US3022233**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 17:03:59

**US3022233**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:09**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '09 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 17:03:59

**US3022233**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:09**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '14:14'	(b) (4), (b) (6)	17 Mar 2021 17:03:59

**US3022233**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User entered '09 Mar 2021 14:14'	System	17 Mar 2021 17:03:59

**US3022233**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 17:04:05



**US3022233**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:34
User entered '1'	System	17 Mar 2021 17:04:05

**US3022233**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 21:57:09**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:09
User entered '09 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 14:05:57

**US3022233**

**Folder: Covid-19 Assessment 09 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 21:57:09**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:09
User entered '09:00'	(b) (4), (b) (6)	12 Oct 2020 14:05:57

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:57:09

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:08
User entered '09 Oct 2020 09:00'	(b) (4), (b) (6) System	12 Oct 2020 14:05:57

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:57:09

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:09
	(b) (4)	
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4), (b) (6)	12 Oct 2020 14:05:57

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:57:09

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:41:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 14:05:57

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	12 Oct 2020 14:07:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
Query 'Thank you for your previous response. If the onset date of symptoms is confirmed as 09OCT2020, please consider if the AE start date should be updated to match.' canceled (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:01:22
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
User opened query 'Thank you for your previous response. If the onset date of symptoms is confirmed as 09OCT2020, please consider if the AE start date should be updated to match.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 01:37:37
User closed query 'Please provide an update as data is overdue. Symptoms began on 02Oct20 per AE but first day on log is 09Oct2020.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 01:37:37
Query 'Please provide an update as data is overdue. Symptoms began on 02Oct20 per AE but first day on log is 09Oct2020.' answered with 'SUBJECT STARTED HAVING ACTUAL SYMPTOMS ON 09OCT2020' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 22:56:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User opened query 'Please provide an update as data is overdue. Symptoms began on 02Oct20 per AE but first day on log is 09Oct2020.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 00:55:39
User closed query 'Per ETRTR: 09Oct20 is the date of Illness Visit D1. Please add log lines for Symptoms prior to Illness Visit (start of symptoms seem to be reported since 02Oct20), thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 00:55:39



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Query 'Per ETRTR: 09Oct20 is the date of Illness Visit D1. Please add log lines for Symptoms prior to Illness Visit (start of symptoms seem to be reported since 02Oct20), thanks.' answered with 'tried to call patient,had to leave message. Will reach out tomorrow to see when symptoms started ' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 20:59:45
User opened query 'Per ETRTR: 09Oct20 is the date of Illness Visit D1. Please add log lines for Symptoms prior to Illness Visit (start of symptoms seem to be reported since 02Oct20), thanks.' (Site from CRA).	(b) (4), (b) (6)	16 Oct 2020 18:57:44
User entered '09 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 14:07:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
User entered '0' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:35:42
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:34:45
User entered '1' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:34:45
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 14:07:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
User entered empty; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '99'	(b) (4), (b) (6)	12 Oct 2020 14:07:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User entered '%'	System	10 Nov 2020 21:39:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered empty.	System	10 Nov 2020 17:17:08
User entered '%'	System	12 Oct 2020 14:07:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
User entered empty; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '37.1' C	(b) (4), (b) (6)	12 Oct 2020 14:07:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:07:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:07:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:07:21



US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:07:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:07:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:07:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:07:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:07:21
	(b) (4), (b) (6)	

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Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Oct 2020 14:07:21
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Oct 2020 14:07:21
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:07:21



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Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:07:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:07:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:07:21

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Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:07:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:57:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:07:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	12 Oct 2020 14:09:27

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
User entered '03 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '10 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 14:09:27
	(b) (4), (b) (6)	

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
User entered '0' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:35:42
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:35:15
User entered '1' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:35:15
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 14:09:27



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
User entered empty; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '99'	(b) (4), (b) (6)	12 Oct 2020 14:09:27

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User entered '%'	System	10 Nov 2020 21:39:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered empty.	System	10 Nov 2020 17:17:08
User entered '%'	System	12 Oct 2020 14:09:27

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:35:42
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 20:23:15
User entered empty; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 20:23:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
User entered empty; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '99.9' F	(b) (4), (b) (6)	12 Oct 2020 14:09:27

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:09:27

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:09:27

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:09:27

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:09:27

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:09:27



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Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:09:27

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:09:27

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:09:27
	(b) (4), (b) (6)	

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Form: Symptom Log (2)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Oct 2020 14:09:27

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Oct 2020 14:09:27

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:09:27

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:09:27

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:09:27



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:09:27

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:09:27

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:57:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:09:27

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	12 Oct 2020 14:10:00

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
User entered '04 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '11 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 14:10:00
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
User entered '0' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:35:42
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:35:00
User entered '1' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:35:00
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 14:10:00

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
User entered empty; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '98'	(b) (4), (b) (6)	12 Oct 2020 14:10:00

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User entered '%'	System	10 Nov 2020 21:39:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered empty.	System	10 Nov 2020 17:17:08
User entered '%'	System	12 Oct 2020 14:10:00



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:25:25
User closed query 'Please confirm - per source no data.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:25:23
Query 'Please confirm - per source no data.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	10 Nov 2020 20:25:04
User entered empty; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 20:23:15
DataPoint Un-verified.	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 20:22:57
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 20:22:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
User opened query 'Please confirm - per source no data.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:11:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
User entered '9' F reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '99.1' F	(b) (4), (b) (6)	12 Oct 2020 14:10:00

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:00

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:00

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:00

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:00

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:00

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:00

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:00



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:00
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Oct 2020 14:10:00
	(b) (4), (b) (6)	

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Oct 2020 14:10:00
	(b) (4), (b) (6)	

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:00

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:00

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:00

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:00

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:00



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Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:57:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:00

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	12 Oct 2020 14:10:23

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
User entered '05 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 14:10:23
	(b) (4), (b) (6)	

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
User entered '0' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:35:42
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:35:00
User entered '1' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:35:00
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 14:10:23

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
User entered empty; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '98'	(b) (4), (b) (6)	12 Oct 2020 14:10:23

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User entered '%'	System	10 Nov 2020 21:39:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered empty.	System	10 Nov 2020 17:17:08
User entered '%'	System	12 Oct 2020 14:10:23

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:35:42
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 20:23:15
User entered empty; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 20:23:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
User entered empty; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '98.3' F	(b) (4), (b) (6)	12 Oct 2020 14:10:23

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:23



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:23

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:23

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:23

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:23

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:23

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:23

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:23
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Oct 2020 14:10:23



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Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Oct 2020 14:10:23
	(b) (4), (b) (6)	

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:23

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:23

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:23

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:23

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:23

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:57:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	12 Oct 2020 14:10:23

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Day 5 (Day 5)'	Shanice Bennett (b) (4)	13 Oct 2020 15:14:23
	(b) (4)	



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
User entered '06 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '13 Oct 2020'	Shanice Bennett (b) (4)	13 Oct 2020 15:14:23
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
User entered '0' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:35:42
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:35:00
User entered '1' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:35:00
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '0'	Shanice Bennett (b) (4) (b) (4)	13 Oct 2020 15:14:23

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
User entered empty; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '98'	Shanice Bennett (b) (4)	13 Oct 2020 15:14:23

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User entered '%'	System	10 Nov 2020 21:39:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered empty.	System	10 Nov 2020 17:17:08
User entered '%'	System	13 Oct 2020 15:14:23

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:35:42
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 20:23:15
User entered empty; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 20:23:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
User entered empty; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '97.3' F	Shanice Bennett (b) (4)	13 Oct 2020 15:14:23

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	Shanice Bennett (b) (4)	13 Oct 2020 15:14:23
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	Shanice Bennett (b) (4)	13 Oct 2020 15:14:23
	(b) (4)	

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Form: Symptom Log (5)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	Shanice Bennett (b) (4)	13 Oct 2020 15:14:23
	(b) (4)	



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Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	Shanice Bennett (b) (4)	13 Oct 2020 15:14:23
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	Shanice Bennett (b) (4)	13 Oct 2020 15:14:23
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	Shanice Bennett (b) (4)	13 Oct 2020 15:14:23
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	13 Oct 2020 15:14:23

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Form: Symptom Log (5)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'None (None)'	Shanice Bennett (b) (4)	13 Oct 2020 15:14:23
	(b) (4)	

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Form: Symptom Log (5)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'Mild (Mild)'	Shanice Bennett (b) (4)	13 Oct 2020 15:14:23
	(b) (4)	

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Form: Symptom Log (5)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'Mild (Mild)'	Shanice Bennett (b) (4)	13 Oct 2020 15:14:23
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	Shanice Bennett (b) (4)	13 Oct 2020 15:14:23
	(b) (4)	



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Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	Shanice Bennett (b) (4)	13 Oct 2020 15:14:23
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'Mild (Mild)'	Shanice Bennett (b) (4)	13 Oct 2020 15:14:23
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	Shanice Bennett (b) (4)	13 Oct 2020 15:14:23
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	Shanice Bennett (b) (4)	13 Oct 2020 15:14:23
	(b) (4)	

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Form: Symptom Log (5)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	Shanice Bennett (b) (4)	13 Oct 2020 15:14:23
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Day 6 (Day 6)'	(b) (4), (b) (6)	15 Oct 2020 17:24:25

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Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
User entered '07 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '14 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 17:24:25
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
User entered '0' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:35:42
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:35:00
User entered '1' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:35:00
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 17:24:25



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
User entered empty; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '99'	(b) (4), (b) (6)	15 Oct 2020 17:24:25

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User entered '%'	System	10 Nov 2020 21:39:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered empty.	System	10 Nov 2020 17:17:08
User entered '%'	System	15 Oct 2020 17:24:25

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:39:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:35:42
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 20:23:15
User entered empty; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 20:23:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
User entered empty; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '95.8' F	(b) (4), (b) (6)	15 Oct 2020 17:24:25

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:24:25

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:24:25

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:24:25

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:24:25

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:24:25



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:24:25

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:24:25

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:24:25

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Oct 2020 17:24:25

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Oct 2020 17:24:25

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:24:25

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:24:25

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User closed query 'Please verify as AE had been entered for nausea from 13-15Oct2020' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 23:57:55
Query 'Please verify as AE had been entered for nausea from 13-15Oct2020' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:15:26
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:15:21
User opened query 'Please verify as AE had been entered for nausea from 13-15Oct2020' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 03:50:02
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:24:25



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:24:25

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:24:25

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:57:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:24:25

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Day 7 (Day 7)'	(b) (4), (b) (6)	15 Oct 2020 17:25:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
User entered '08 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 17:25:30
	(b) (4), (b) (6)	

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Form: Symptom Log (7)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:38:57
User entered '0' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:38:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:35:42
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:35:00
User entered '1' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:35:00
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 17:25:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 21:38:57
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 21:38:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:25:36
User closed query 'Please confirm - per source no data as this was before the illness visit?' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:25:34
Query 'Please confirm - per source no data as this was before the illness visit?' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:24:43
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:24:33
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:24:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User opened query 'Please confirm - per source no data as this was before the illness visit?' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:12:42
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 20:12:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '98'	(b) (4), (b) (6)	15 Oct 2020 17:25:30

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Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User entered '%'	System	10 Nov 2020 21:38:57
User entered empty.	System	10 Nov 2020 20:24:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered '%'	System	15 Oct 2020 17:25:30



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:52:21
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 21:38:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 21:38:57
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:25:37
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:24:33
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:24:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '98.1' F	(b) (4), (b) (6)	15 Oct 2020 17:25:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:25:30

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:25:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:25:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:25:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:25:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:25:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:25:30



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:25:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Oct 2020 17:25:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Oct 2020 17:25:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:25:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:25:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User closed query 'Please confirm.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:34:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:34:04
Query 'Please confirm.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:33:52
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:33:43
User opened query 'Please confirm.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:26:39
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 20:26:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:25:40
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:24:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:24:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:40:44
User closed query 'Please confirm. Per telephone call source no nausea is noted.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 01:40:43
Query 'Please confirm. Per telephone call source no nausea is noted.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 22:57:55
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 22:57:40
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:57:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User opened query 'Please confirm. Per telephone call source no nausea is noted.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 19:14:10
User closed query 'Please verify as AE had been entered for nausea 13-15Oct2020' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 23:58:07

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Query 'Please verify as AE had been entered for nausea 13-15Oct2020' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:15:47
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:15:41
User opened query 'Please verify as AE had been entered for nausea 13-15Oct2020' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 03:50:23
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:25:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:25:30



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Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:25:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:57:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	15 Oct 2020 17:25:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Day 8 (Day 8)'	(b) (4), (b) (6)	19 Oct 2020 19:58:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
User entered '09 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '16 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 19:58:30
	(b) (4), (b) (6)	

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Form: Symptom Log (8)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 19:58:30

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Form: Symptom Log (8)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '99'	(b) (4), (b) (6)	19 Oct 2020 19:58:30

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Form: Symptom Log (8)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered '%'	System	19 Oct 2020 19:58:30

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Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:13:03
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:35:30
	(b) (4)	
User entered '37.1' C reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:35:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '96.8' F	(b) (4), (b) (6)	19 Oct 2020 19:58:30
	(b) (4), (b) (6)	



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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	19 Oct 2020 19:58:30

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Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	19 Oct 2020 19:58:30

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Generated On: 11 Aug 2021 21:57:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	19 Oct 2020 19:58:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	19 Oct 2020 19:58:30

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	19 Oct 2020 19:58:30

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	19 Oct 2020 19:58:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	19 Oct 2020 19:58:30

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	19 Oct 2020 19:58:30



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:13:07
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:35:30
	(b) (4)	
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:35:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Oct 2020 19:58:30
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:13:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:35:30
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:35:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'Mild (Mild)'	(b) (4), (b) (6)	19 Oct 2020 19:58:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	19 Oct 2020 19:58:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	19 Oct 2020 19:58:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	19 Oct 2020 19:58:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	19 Oct 2020 19:58:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	19 Oct 2020 19:58:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:57:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	19 Oct 2020 19:58:30



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	20 Oct 2020 13:48:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
User entered '10 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '17 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 13:48:57
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 13:48:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '99'	(b) (4), (b) (6)	20 Oct 2020 13:48:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered '%'	System	20 Oct 2020 13:48:57

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:35:30
	(b) (4)	
User entered '99.9' F reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:35:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '98.2' F	(b) (4), (b) (6)	20 Oct 2020 13:48:57
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:48:57

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:48:57



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:48:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:48:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:48:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:48:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:48:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:48:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:35:30
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:35:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Oct 2020 13:48:57

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:35:30
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:35:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Oct 2020 13:48:57



US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:48:57

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:48:57

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:48:57

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:48:57

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:48:57

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:57:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:48:57

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	20 Oct 2020 13:49:26

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
User entered '11 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '18 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 13:49:26
	(b) (4), (b) (6)	



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 13:49:26

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:13:43
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:35:30
	(b) (4)	
User entered '98' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:35:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '99'	(b) (4), (b) (6)	20 Oct 2020 13:49:26
	(b) (4), (b) (6)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered '%'	System	20 Oct 2020 13:49:26

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:13:45
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:35:30
	(b) (4)	
User entered '99.1' F reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:35:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '98.2' F	(b) (4), (b) (6)	20 Oct 2020 13:49:26
	(b) (4), (b) (6)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:26

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:26

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:26

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:26



US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:26

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:26

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:26

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:26

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:13:49
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:35:30
	(b) (4)	
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:35:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Oct 2020 13:49:26
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:13:51
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:35:30
	(b) (4)	
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:35:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Oct 2020 13:49:26
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:26

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:26



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:26

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:26

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:26

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:57:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:26

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Day 11 (Day 11)'	(b) (4), (b) (6)	20 Oct 2020 13:49:52

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
User entered '12 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '19 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 13:49:52
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 13:49:52

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:14:03
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:42:25
	(b) (4)	
User entered '98' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:42:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '99'	(b) (4), (b) (6)	20 Oct 2020 13:49:52
	(b) (4), (b) (6)	



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered '%'	System	20 Oct 2020 13:49:52

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:14:05
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:42:25
	(b) (4)	
User entered '98.3' F reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:42:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '97.6' F	(b) (4), (b) (6)	20 Oct 2020 13:49:52
	(b) (4), (b) (6)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:52

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:52

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:52

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:52

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:52

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:52



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:52

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:52

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:14:09
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Oct 2020 13:49:52
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:14:11
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Oct 2020 13:49:52
	(b) (4), (b) (6)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:52

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:52

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:52

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:52



US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:52

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:57:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:49:52

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Day 12 (Day 12)' reason for change:	(b) (4), (b) (6)	21 Oct 2020 20:02:30
Data Entry Error		
User entered 'Day 20 (Day 20)'	(b) (4), (b) (6)	20 Oct 2020 13:50:16

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:14:49
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
User entered '13 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '20 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 13:50:16
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 13:50:16

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '98'	(b) (4), (b) (6)	20 Oct 2020 13:50:16

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered '%'	System	20 Oct 2020 13:50:16

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:14:51
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:42:25
	(b) (4)	
User entered '97.3' F reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:42:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '97.6' F	(b) (4), (b) (6)	20 Oct 2020 13:50:16
	(b) (4), (b) (6)	



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:50:16

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:50:16

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:50:16

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:50:16

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:50:16

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:50:16

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:50:16

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:50:16



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:14:45
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:42:25
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:50:16

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:14:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:42:25
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:50:16

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:50:16

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:50:16

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:14:43
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:50:16
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:50:16

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:50:16

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:57:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 13:50:16



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User closed query 'Please verify and enter symptom day' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 23:58:48
Query 'Please verify and enter symptom day' answered with 'UPATED' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:16:28
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:16:20
User opened query 'Please verify and enter symptom day' (Site from CRA).	(b) (4), (b) (6)	25 Oct 2020 23:17:09
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:02:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
User entered '14 Oct 2020' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:04:13
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 20:03:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 20:03:39
User entered '21 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:03:39
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 20:02:30
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:02:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 20:02:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:42:25
User entered '99' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:42:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '93' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:03:39
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:02:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered '%'	System	21 Oct 2020 20:03:39
User entered empty.	System	21 Oct 2020 20:02:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:42:25
User entered '95.8' F reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:42:25
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '97.5' C reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:03:39
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:02:30

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:03:39
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:02:30

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:03:39
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:02:30



US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:03:39
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:02:30

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:03:39
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:02:30

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:03:39
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:02:30

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:03:39
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:02:30

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:03:39
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:02:30

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:03:39
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:02:30

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:42:25
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:03:39
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:02:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:42:25
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:03:39
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:02:30



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:03:39
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:02:30

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:03:39
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:02:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:03:39
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:02:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:03:39
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:02:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:03:39
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:02:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:57:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:03:39
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:02:30

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Day 14 (Day 14)'	(b) (4), (b) (6)	22 Oct 2020 18:08:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
User entered '15 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '22 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 18:08:57
	(b) (4), (b) (6)	



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Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 18:08:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:42:25
	(b) (4)	
User entered '98' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:42:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '99'	(b) (4), (b) (6)	22 Oct 2020 18:08:57
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered '%'	System	22 Oct 2020 18:08:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:42:25
	(b) (4)	
User entered '98.1' F reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:42:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '97.5' F	(b) (4), (b) (6)	22 Oct 2020 18:08:57
	(b) (4), (b) (6)	

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Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	22 Oct 2020 18:08:57

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Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	22 Oct 2020 18:08:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	22 Oct 2020 18:08:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	22 Oct 2020 18:08:57



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	22 Oct 2020 18:08:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	22 Oct 2020 18:08:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	22 Oct 2020 18:08:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	22 Oct 2020 18:08:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:42:25
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	22 Oct 2020 18:08:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:42:25
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	22 Oct 2020 18:08:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	22 Oct 2020 18:08:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	22 Oct 2020 18:08:57



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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:28:12
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 20:27:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:42:25
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	22 Oct 2020 18:08:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	22 Oct 2020 18:08:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	22 Oct 2020 18:08:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:57:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	22 Oct 2020 18:08:57

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Day 15 (Day 15)'	(b) (4), (b) (6)	26 Oct 2020 19:03:03

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
User entered '16 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '23 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 19:03:03
	(b) (4), (b) (6)	

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Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 19:03:03

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '99'	(b) (4), (b) (6)	26 Oct 2020 19:03:03



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered '%'	System	26 Oct 2020 19:03:03

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:42:25
	(b) (4)	
User entered '96.8' F reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:42:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '98.1' F	(b) (4), (b) (6)	26 Oct 2020 19:03:03
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:03:03

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:03:03

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:03:03

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:03:03

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:03:03

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Form: Symptom Log (15)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:03:03



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Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:03:03

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:03:03

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:42:25
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:03:03

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:42:25
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:03:03

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:03:03

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:03:03

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:03:03

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:03:03



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:03:03

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:57:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:03:03

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Day 16 (Day 16)'	(b) (4), (b) (6)	26 Oct 2020 19:04:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
User entered '17 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '24 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 19:04:18
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 19:04:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:42:25
	(b) (4)	
User entered '99' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:42:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '98'	(b) (4), (b) (6)	26 Oct 2020 19:04:18
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered '%'	System	26 Oct 2020 19:04:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:42:25
	(b) (4)	
User entered '98.2' F reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:42:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '97.8' F	(b) (4), (b) (6)	26 Oct 2020 19:04:18
	(b) (4), (b) (6)	



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:04:18

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:04:18

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:04:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:04:18

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:04:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:04:18

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:04:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:04:18



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:42:25
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:04:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:42:25
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:04:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:04:18

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Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:04:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:04:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:04:18

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:04:18

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:57:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:04:18



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Day 17 (Day 17)'	(b) (4), (b) (6)	26 Oct 2020 19:06:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
User entered '18 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '25 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 19:06:21
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 19:06:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:49:09
	(b) (4)	
User entered '99' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:49:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '98'	(b) (4), (b) (6)	26 Oct 2020 19:06:21
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered '%'	System	26 Oct 2020 19:06:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:49:09
	(b) (4)	
User entered '98.2' F reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:49:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '97.6' F	(b) (4), (b) (6)	26 Oct 2020 19:06:21
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:06:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:06:21



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:06:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:06:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:06:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:06:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:06:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:06:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:06:21
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:06:21
	(b) (4), (b) (6)	



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:06:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:06:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:06:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:06:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:06:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:57:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:06:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'Day 18 (Day 18)'	(b) (4), (b) (6)	26 Oct 2020 19:07:47

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
User entered '19 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 19:07:47
	(b) (4), (b) (6)	



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 19:07:47

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:49:09
	(b) (4)	
User entered '99' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:49:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '98'	(b) (4), (b) (6)	26 Oct 2020 19:07:47
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered '%'	System	26 Oct 2020 19:07:47

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '97.6' F	(b) (4), (b) (6)	26 Oct 2020 19:07:47

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:07:47

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:07:47

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:07:47

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:07:47



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:07:47

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:07:47

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:07:47

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:07:47

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:07:47
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:07:47
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:07:47

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:07:47



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:07:47

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:07:47

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:07:47

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:57:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	26 Oct 2020 19:07:47

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User closed query 'Thank you for your previous response of not captured. Please add another log line capturing Day 20 and tick not done.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:17:38
Query 'Thank you for your previous response of not captured. Please add another log line capturing Day 20 and tick not done.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:59:45
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User opened query 'Thank you for your previous response of not captured. Please add another log line capturing Day 20 and tick not done.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 01:42:52
User closed query 'Please enter Day 20 information.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 01:42:52
Query 'Please enter Day 20 information.' answered with 'DAY 20 NOT CAPTURED' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 23:00:07
User opened query 'Please enter Day 20 information.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 18:31:59
User entered 'Day 19 (Day 19)'	(b) (4), (b) (6)	28 Oct 2020 18:11:09

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
User entered '20 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:21:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '27 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 18:11:09
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 18:11:09

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered '98'	(b) (4), (b) (6)	28 Oct 2020 18:11:09



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered '%'	System	28 Oct 2020 18:11:09

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
	(b) (4), (b) (6)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 17:49:09
	(b) (4)	
User entered '97.6' F reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 17:49:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
	(b) (4), (b) (6)	
User entered '97.5' F	(b) (4), (b) (6)	28 Oct 2020 18:11:09
	(b) (4), (b) (6)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 18:11:09

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 18:11:09

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 18:11:09

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 18:11:09

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 18:11:09

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 18:11:09



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 18:11:09

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 18:11:09

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:49:09
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 18:11:09

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
User entered 'None (None)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:49:09
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
User entered 'Mild (Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 17:21:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 18:11:09

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 18:11:09

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 18:11:09

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 18:11:09

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 18:11:09



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 18:11:09

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:57:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 19:29:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	10 Nov 2020 19:28:43
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:04:13
User entered 'None (None)'	(b) (4), (b) (6)	28 Oct 2020 18:11:09

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Day 20 (Day 20)'	Shanice Bennett (b) (4)	10 Nov 2020 19:58:43
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered '21 Oct 2020'	Shanice Bennett (b) (4)	10 Nov 2020 19:58:43
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 19:58:43
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered '93'	Shanice Bennett (b) (4)	10 Nov 2020 19:58:43
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User entered '%'	(b) (4), (b) (6) System	10 Nov 2020 19:58:43

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered '97.5' F	Shanice Bennett (b) (4)	10 Nov 2020 19:58:43
	(b) (4)	



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Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 19:58:43
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 19:58:43
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 19:58:43
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 19:58:43
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 19:58:43
	(b) (4)	

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Form: Symptom Log (28)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 19:58:43
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 19:58:43
	(b) (4)	

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Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 19:58:43
	(b) (4)	



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Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 19:58:43
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 19:58:43
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 19:58:43
	(b) (4)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:58:43

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 19:58:43
	(b) (4)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 19:58:43
	(b) (4)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 19:58:43
	(b) (4)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 21:57:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 19:58:43
	(b) (4)	



US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Day 21 (Day 21)'	Shanice Bennett (b) (4)	10 Nov 2020 20:02:01
	(b) (4)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered '22 Oct 2020'	Shanice Bennett (b) (4)	10 Nov 2020 20:02:01
	(b) (4)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 20:02:01
	(b) (4)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered '99'	Shanice Bennett (b) (4)	10 Nov 2020 20:02:01
	(b) (4)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User entered '%'	(b) (4), (b) (6) System	10 Nov 2020 20:02:01

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered '97.5' F	Shanice Bennett (b) (4)	10 Nov 2020 20:02:01
	(b) (4)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 20:02:01
	(b) (4)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 20:02:01
	(b) (4)	



US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 20:02:01
	(b) (4)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 20:02:01
	(b) (4)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 20:02:01
	(b) (4)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:02:01

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 20:02:01
	(b) (4)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 20:02:01
	(b) (4)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 20:02:01
	(b) (4)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 20:02:01
	(b) (4)	



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 20:02:01
	(b) (4)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:02:01

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 20:02:01
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 20:02:01
	(b) (4)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 20:02:01
	(b) (4)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Symptom Log (29)

Generated On: 11 Aug 2021 21:57:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:33
User entered 'None (None)'	Shanice Bennett (b) (4)	10 Nov 2020 20:02:01
	(b) (4)	

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Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:57:09

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:25
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:43:56
Query 'Per GCL Lab Recon (Re-Query): previous response is noted; however, please confirm if Unscheduled Visit Biofire (09OCT2020) is actually Illness Day 1 Swab sample (09OCT2020) or clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 22:11:04
User opened query 'Per GCL Lab Recon (Re-Query): previous response is noted; however, please confirm if Unscheduled Visit Biofire (09OCT2020) is actually Illness Day 1 Swab sample (09OCT2020) or clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:15:02
Query 'Per GCL Lab Recon (Re-Query): please confirm if Unscheduled Visit COVID (09OCT2020) is actually Illness Day 1 sample (09OCT2020) or clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:14:56
User opened query 'Per GCL Lab Recon (Re-Query): please confirm if Unscheduled Visit COVID (09OCT2020) is actually Illness Day 1 sample (09OCT2020) or clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:14:14
Query 'Per GCL Lab Recon (Re-Query): previous response is noted; however, please confirm if Unscheduled Visit Biofire (09OCT2020) is actually Illness Day 1 Swab sample (09OCT2020) or clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:13:41
User opened query 'Per GCL Lab Recon (Re-Query): previous response is noted; however, please confirm if Unscheduled Visit Biofire (09OCT2020) is actually Illness Day 1 Swab sample (09OCT2020) or clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 03:51:39
User closed query 'Per GCL Reconciliation: Swab sample collected on 09OCT2020 is labelled under "Unscheduled Visit Biofire" in Viracor data and in GCL it is labelled under "Illness D1". Please verify the correct visit for sample collected on this date." (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 22:07:27

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Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:57:09

[Date of Visit](#)

Audit	User	Time (GMT)
Query 'Per GCL Reconciliation: Swab sample collected on 09OCT2020 is labelled under "Unscheduled Visit Biofire" in Viracor data and in GCL it is labelled under "Illness D1". Please verify the correct visit for sample collected on this date.' answered with 'DATE IS CORRECT 09OCT2020' (Site from DM).	Shanice Bennett (b) (4)	03 Nov 2020 21:16:30
User opened query 'Per GCL Reconciliation: Swab sample collected on 09OCT2020 is labelled under "Unscheduled Visit Biofire" in Viracor data and in GCL it is labelled under "Illness D1". Please verify the correct visit for sample collected on this date.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:11:52
Query 'Per GCL Reconciliation: Swab sample collected on 09OCT2020 is labelled under "Unscheduled Visit Biofire & Unscheduled Visit COVID" in Viracor data and in GCL it is labelled under "Illness D1 & Visit 1 Day 1". Please verify the correct visit for sample collected on this date.' canceled (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:11:13
User opened query 'Per GCL Reconciliation: Swab sample collected on 09OCT2020 is labelled under "Unscheduled Visit Biofire & Unscheduled Visit COVID" in Viracor data and in GCL it is labelled under "Illness D1 & Visit 1 Day 1". Please verify the correct visit for sample collected on this date.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:09:59
Query 'Per GCL Reconciliation: Swab sample collected on 09OCT2020 is labelled under "Unscheduled Visit COVID" in Viracor data and in GCL it is labelled under "Illness D1". Please verify the correct visit for sample collected on this date.' canceled (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:09:49
User opened query 'Per GCL Reconciliation: Swab sample collected on 09OCT2020 is labelled under "Unscheduled Visit COVID" in Viracor data and in GCL it is labelled under "Illness D1". Please verify the correct visit for sample collected on this date.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:00:36
User entered '09 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 14:08:16



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Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:57:09

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 14:08:16

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:57:09

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:25
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:43:56
User closed query 'Per CDM: Please enter COVID-19 diagnosis on the AE form. Or explain/reconcile.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:31:37
Query 'Per CDM: Please enter COVID-19 diagnosis on the AE form. Or explain/reconcile.' answered with 'UPDATED' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	03 Nov 2020 21:16:39
User opened query 'Per CDM: Please enter COVID-19 diagnosis on the AE form. Or explain/reconcile.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	14 Oct 2020 19:27:51
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) (b) (4), (b) (6)	14 Oct 2020 19:26:38
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'updated' (Site from System).	Shanice Bennett (b) (4) (b) (4)	13 Oct 2020 15:10:33
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	13 Oct 2020 15:10:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	13 Oct 2020 15:10:22
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 14:08:16

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:57:09

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:56
User entered '09 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 14:08:16

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Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:57:09

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:56
User entered 'Nasal Swab (Nasal Swab)'	(b) (4), (b) (6)	12 Oct 2020 14:08:16

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:57:09

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:56
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:08:16

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:57:09

[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)	29 Apr 2021 22:00:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:56
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 14:08:16

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:57:09

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:56
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:08:16

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:57:09

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:43:56
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 14:08:16



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Folder: Covid-19 Assessment 09 Oct 2020

Form: COVID Diagnostic Test

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COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:25
User entered '1'	(b) (4), (b) (6)	
	System	13 Oct 2020 15:10:22
User entered '0'	System	12 Oct 2020 14:08:16

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	05 Mar 2021 23:01:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:44:04
User closed query 'Please verify as Day 13 on symptom log notes SpO2 of 93%' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 00:56:26
Query 'Please verify as Day 13 on symptom log notes SpO2 of 93%' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4) (b) (4)	06 Nov 2020 15:27:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	06 Nov 2020 15:26:35
User opened query 'Please verify as Day 13 on symptom log notes SpO2 of 93%' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 03:47:15
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered '21 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	06 Nov 2020 15:26:35
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered '21 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	06 Nov 2020 15:26:35
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered '93' reason for change: Data Entry Error	Shanice Bennett (b) (4)	06 Nov 2020 15:26:35
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21



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Form: Covid-19 Severity Assessment

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:19:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
User closed query 'Per CDM re-query: Response noted; however these fields are required only if 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is Yes. Kindly consider leaving these fields empty. Otherwise clarify. Thank you.' (Site from DM).	(b) (4)	04 Mar 2021 04:33:02
Query 'Per CDM re-query: Response noted; however these fields are required only if 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is Yes. Kindly consider leaving these fields empty. Otherwise clarify. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 16:06:10
DataPoint Un-verified.	(b) (4), (b) (6)	03 Mar 2021 16:05:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 16:05:55
User opened query 'Per CDM re-query: Response noted; however these fields are required only if 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is Yes. Kindly consider leaving these fields empty. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:33:02
User closed query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:31:14

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly. ' answered with 'NO SUBJECT HAD NEITHER ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 16:15:20
User opened query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 22:03:07
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

Non-Invasive Ventilation?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:20:00
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
DataPoint Un-verified.	(b) (4), (b) (6)	03 Mar 2021 16:05:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 16:05:55
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:20:00
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
DataPoint Un-verified.	(b) (4), (b) (6)	03 Mar 2021 16:05:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 16:05:55
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:20:00
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	03 Mar 2021 16:05:55
	(b) (4), (b) (6)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 16:05:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:32:21
	(b) (4), (b) (6)	



US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:20:00
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
DataPoint Un-verified.	(b) (4), (b) (6)	03 Mar 2021 16:05:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 16:05:55
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:32:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

Evidence of Shock Requires  
Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:20:00
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
DataPoint Un-verified.	(b) (4)	03 Mar 2021 16:05:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 16:05:55
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:32:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21



US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:20:00
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
DataPoint Un-verified.	(b) (4), (b) (6)	03 Mar 2021 16:05:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 16:05:55
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:32:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:20:00
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	03 Mar 2021 16:05:55
	(b) (4), (b) (6)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 16:05:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:32:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:20:00
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
DataPoint Un-verified.	(b) (4), (b) (6)	03 Mar 2021 16:05:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 16:05:55
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:32:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:20:00
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
DataPoint Un-verified.	(b) (4), (b) (6)	03 Mar 2021 16:05:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 16:05:55
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:32:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21



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Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:20:00
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	03 Mar 2021 16:05:55
	(b) (4), (b) (6)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 16:05:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:32:21
	(b) (4), (b) (6)	

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:20:00
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 16:06:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 16:06:02
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 16:05:55
DataPoint Un-verified.	(b) (4), (b) (6)	03 Mar 2021 16:05:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 16:05:55
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 20:32:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:57:09

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:01:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:04
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:32:21

US3022233

Folder: Covid-19 Assessment 09 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 21:57:09

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:00:39
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:44:38
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 14:08:21

**US3022233**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	19 Oct 2020 20:16:53

US3022233

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:57:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:23:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 20:16:53



US3022233

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:57:09

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:23:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered '11 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 20:16:53

**US3022233**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	19 Oct 2020 20:16:53

US3022233

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:57:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:23:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 20:16:53

**US3022233**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:23:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered '13 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 20:16:53

US3022233

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:57:09

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Please verify and enter Day 9 Saliva sample information' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 23:59:13
Query 'Please verify and enter Day 9 Saliva sample information' answered with 'UPDATED' (Site from CRA).	Shanice Bennett (b) (4)	03 Nov 2020 21:13:59
User opened query 'Please verify and enter Day 9 Saliva sample information' (Site from CRA).	(b) (4), (b) (6)	25 Oct 2020 23:17:45
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	19 Oct 2020 20:16:53

US3022233

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:57:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:23:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 20:16:53

US3022233

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:57:09

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:23:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User closed query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, thank you for confirming the Accession number. Please confirm tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:38:27
Query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, thank you for confirming the Accession number. Please confirm tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'Site has already received results' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 18:42:29
User opened query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, thank you for confirming the Accession number. Please confirm tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 11:53:18
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15,22,29OCT2020 is recorded under Illness Visit Day 7,14,21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 10:13:53

US3022233

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:57:09

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15,22,29OCT2020 is recorded under Illness Visit Day 7,14,21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with '1F603073766' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 19:23:56
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15,22,29OCT2020 is recorded under Illness Visit Day 7,14,21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 04:34:58
User entered '15 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 20:16:53



**US3022233**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 21:57:09**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	19 Oct 2020 20:16:53

US3022233

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:57:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:23:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	03 Nov 2020 21:15:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 07:16:36
Query 'Data is required. Please complete.' answered with 'has not been collected yet ' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 20:19:23
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 20:16:53
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:16:53

US3022233

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:57:09

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:23:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered '17 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	03 Nov 2020 21:15:38
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:16:53

**US3022233**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 21:57:09**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	19 Oct 2020 20:16:53

US3022233

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:57:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:23:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User closed query 'Per GCL LAB reconciliation: Thank you for the response. Saliva: PPD reports Day 14 sample with Accession # 1F621605994 is reported with 13oct2020 date of Collection. Please confirm in the response the correct date for the Day 14 as EDC is 22OCT2020 and 13Oct2020 which was reported in PPD.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 05:33:38
Query 'Per GCL LAB reconciliation: Thank you for the response. Saliva: PPD reports Day 14 sample with Accession # 1F621605994 is reported with 13oct2020 date of Collection. Please confirm in the response the correct date for the Day 14 as EDC is 22OCT2020 and 13Oct2020 which was reported in PPD.' answered with 'THIS DATE IS CORRECT AND SITE HAS ALREADY RECEIVED LAB RESULTS FOR THAT ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 13:53:54
User opened query 'Per GCL LAB reconciliation: Thank you for the response. Saliva: PPD reports Day 14 sample with Accession # 1F621605994 is reported with 13oct2020 date of Collection. Please confirm in the response the correct date for the Day 14 as EDC is 22OCT2020 and 13Oct2020 which was reported in PPD.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 06:40:17
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F621605994 is reported with 13oct2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 06:26:18

US3022233

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:57:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F621605994 is reported with 13oct2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with 'this is correct. the accession number is different from the barcode number' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 15:51:36
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 14 sample with Accession # 1F621605994 is reported with 13oct2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:40:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	03 Nov 2020 21:15:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 07:16:39
Query 'Data is required. Please complete.' answered with 'has not been collected yet' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 20:19:39
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 20:16:53
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:16:53

US3022233

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:57:09

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:23:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User closed query 'Per GCL LAB reconciliation: Saliva: DAY 14 visit sample dated 22OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:39:30
Query 'Per GCL LAB reconciliation: Saliva: DAY 14 visit sample dated 22OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'Site has already received results' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 18:42:40
User opened query 'Per GCL LAB reconciliation: Saliva: DAY 14 visit sample dated 22OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 11:53:57
User entered '22 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	03 Nov 2020 21:15:38
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:16:53

**US3022233**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	19 Oct 2020 20:16:53



US3022233

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:57:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:23:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User closed query 'Per GCL LAB reconciliation: Saliva: Re-query DAY 21 visit sample dated 29OCT2020 is still missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the "Accession number" and "tracking number" with shipping date to track the sample in PPD' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 11:23:44
Query 'Per GCL LAB reconciliation: Saliva: Re-query DAY 21 visit sample dated 29OCT2020 is still missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the "Accession number" and "tracking number" with shipping date to track the sample in PPD' answered with 'will check with lab' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 16:37:42
User opened query 'Per GCL LAB reconciliation: Saliva: Re-query DAY 21 visit sample dated 29OCT2020 is still missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the "Accession number" and "tracking number" with shipping date to track the sample in PPD' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:44:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	03 Nov 2020 21:15:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 07:16:42
Query 'Data is required. Please complete.' answered with 'has not been collected yet ' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 20:19:48
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 20:16:53
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:16:53

US3022233

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:57:09

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:23:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User closed query 'Per GCL LAB reconciliation: Saliva: DAY 21 visit sample dated 29OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:41:23
Query 'Per GCL LAB reconciliation: Saliva: DAY 21 visit sample dated 29OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'Site has already received results' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 18:42:47
User opened query 'Per GCL LAB reconciliation: Saliva: DAY 21 visit sample dated 29OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 11:54:22
User entered '29 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	03 Nov 2020 21:15:38
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:16:53

**US3022233**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	19 Oct 2020 20:16:53

US3022233

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:57:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:23:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 20:04:45
User closed query 'Per CDM; Please confirm no Saliva sample was collected for Day 28 or update appropriately. Also, it appears a Convalescence Visit Day 28 may be needed. Please reconcile and add or clarify.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:15:20
Query 'Per CDM; Please confirm no Saliva sample was collected for Day 28 or update appropriately. Also, it appears a Convalescence Visit Day 28 may be needed. Please reconcile and add or clarify.' answered with 'DAY 28 NOT NEEDED' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:54:54
User opened query 'Per CDM; Please confirm no Saliva sample was collected for Day 28 or update appropriately. Also, it appears a Convalescence Visit Day 28 may be needed. Please reconcile and add or clarify.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 11:34:25
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	03 Nov 2020 21:15:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 07:16:45
Query 'Data is required. Please complete.' answered with 'has not been collected yet ' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 20:19:56
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 20:16:53
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:16:53

US3022233

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:57:09

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:23:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered '09 Nov 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 20:04:45
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:16:53

**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:45:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 20:05:58

**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:45:42
User entered '09 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 20:05:58

**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:45:42
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Oct 2020 20:05:58



**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	19 Oct 2020 20:05:58

**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:46:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 20:07:29

**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:46:09
User entered '09 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 20:07:29

**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:46:09
User entered '11:53'	(b) (4), (b) (6)	19 Oct 2020 20:07:29

**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:53'	System	19 Oct 2020 20:07:29

US3022233

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 01:44:45
User closed query 'Please confirm this was captured on 9Oct2020.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 01:44:42
Query 'Please confirm this was captured on 9Oct2020.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 22:47:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:47:13
User opened query 'Please confirm this was captured on 9Oct2020.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 17:46:46
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 17:46:27
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:46:09
User entered '167.6' cm	(b) (4), (b) (6)	19 Oct 2020 20:07:29
DataPoint set to visible.	System	19 Oct 2020 20:05:58

US3022233

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 01:44:47
User closed query 'Please confirm this was captured on 9Oct2020.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 01:44:44
Query 'Please confirm this was captured on 9Oct2020.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 22:47:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 22:47:13
User opened query 'Please confirm this was captured on 9Oct2020.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 17:46:50
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 17:46:33
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:46:09
User entered '76.6' kg	(b) (4), (b) (6)	19 Oct 2020 20:07:29
DataPoint set to visible.	System	19 Oct 2020 20:05:58

**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:46:09
User entered '37.1' C	(b) (4), (b) (6)	19 Oct 2020 20:07:29



**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:46:09
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Oct 2020 20:07:29

**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:46:09
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:07:29

**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:46:09
User entered '79'	(b) (4), (b) (6)	19 Oct 2020 20:07:29

**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Oct 2020 20:07:29

**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:46:09
User entered '15'	(b) (4), (b) (6)	19 Oct 2020 20:07:29

**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Oct 2020 20:07:29

**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:46:09
User entered '114'	(b) (4), (b) (6)	19 Oct 2020 20:07:29

**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Oct 2020 20:07:29



**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:46:09
User entered '75'	(b) (4), (b) (6)	19 Oct 2020 20:07:29

**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Oct 2020 20:07:29

**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:57:09**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:47:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 20:07:39

**US3022233**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:57:09**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:47:08
User entered '09 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 20:07:39

US3022233

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:57:09

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:47:19
Query 'Per GCL Lab Recon (Re-Query): please confirm if Unscheduled Visit COVID (09OCT2020) is actually Illness Day 1 SARS-CoV-2 sample (09OCT2020) or clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:15:23
User opened query 'Per GCL Lab Recon (Re-Query): please confirm if Unscheduled Visit COVID (09OCT2020) is actually Illness Day 1 SARS-CoV-2 sample (09OCT2020) or clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:03:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 20:07:57

US3022233

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:57:09

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:47:19
User entered '09 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 20:07:57

**US3022233**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:20:18
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:03:13

**US3022233**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:20:18
User entered '09 Nov 2020'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:03:13



US3022233

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:57:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:20:18
User entered 'Clinic (Clinic)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:03:13

**US3022233**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	10 Nov 2020 20:03:13

US3022233

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:20:47
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:04:06

US3022233

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:20:47
User entered '09 Nov 2020'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:04:06

**US3022233**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:20:47
User entered '15:38'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:04:06

**US3022233**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020 15:38'	System	10 Nov 2020 20:04:06

US3022233

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

Height (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:20:47
User entered '167.6' cm	Shanice Bennett (b) (4)	10 Nov 2020 20:04:06
DataPoint set to visible.	(b) (4) System	10 Nov 2020 20:03:13

US3022233

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:20:47
User entered '78.4' kg	Shanice Bennett (b) (4)	10 Nov 2020 20:04:06
DataPoint set to visible.	(b) (4) System	10 Nov 2020 20:03:13



**US3022233**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:20:47
User entered '36.6' C	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:04:06

US3022233

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:20:47
User entered 'Oral (Oral)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:04:06

**US3022233**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:20:47
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:04:06

US3022233

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:20:47
User entered '77'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:04:06

**US3022233**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Nov 2020 20:04:06

**US3022233**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:20:47
User entered '15'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:04:06

**US3022233**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Nov 2020 20:04:06

US3022233

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:20:47
User entered '121'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:04:06



**US3022233**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Nov 2020 20:04:06

US3022233

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:57:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:20:47
User entered '80'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:04:06

**US3022233**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:57:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Nov 2020 20:04:06

US3022233

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:21:01
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:04:17

US3022233

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:09

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:21:01
User entered '09 Nov 2020'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:04:17

US3022233

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:57:09

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:21:08
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:04:30

US3022233

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:57:09

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:21:08
User entered '09 Nov 2020'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:04:30

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:28:35



**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:28:35

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:57:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:28:35

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered 'UNBLND_DECIDE'	System	27 Jan 2021 18:28:35

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:57:09

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:28:49

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:57:09**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:07
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 18:28:45
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:23:13

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:57:09**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:28:49

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:57:09

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:07
	(b) (4)	
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 14:42:28
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 18:29:00
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 18:28:45
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)	09 Apr 2021 13:55:45
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:23:13

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:57:09

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '26 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 18:28:49



US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:57:09

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	27 Jan 2021 18:28:49

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:57:09**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	27 Jan 2021 18:28:49

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:57:09**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	27 Jan 2021 18:28:49

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:57:09**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:28:49

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:57:09**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered '1'	(b) (4), (b) (6) System	27 Jan 2021 18:28:49

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:57:09**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered '1'	(b) (4), (b) (6) System	27 Jan 2021 18:28:49

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:57:09**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Jan 2021 18:30:17

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:57:09**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Jan 2021 18:30:17



US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:57:09

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered empty.	(b) (4), (b) (6)	
	System	27 Jan 2021 18:30:17
DataPoint set to visible.	System	27 Jan 2021 18:28:49

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:57:09**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Jan 2021 18:30:17

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:57:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Jan 2021 18:30:17

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:57:09**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered empty.	(b) (4), (b) (6)	
DataPoint set to visible.	System	27 Jan 2021 18:30:17
	System	27 Jan 2021 18:28:49

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	27 Jan 2021 18:30:17

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:30:17

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '26 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 18:30:17

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '16:04'	(b) (4), (b) (6)	27 Jan 2021 18:30:17



**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered '26 Jan 2021 16:04'	(b) (4), (b) (6) System	27 Jan 2021 18:30:17

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '37.0' C	(b) (4), (b) (6)	27 Jan 2021 18:30:17

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	27 Jan 2021 18:30:17

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:30:17

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '73'	(b) (4), (b) (6)	27 Jan 2021 18:30:17

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered 'bpm'	(b) (4), (b) (6) System	27 Jan 2021 18:30:17

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '18'	(b) (4), (b) (6)	27 Jan 2021 18:30:17

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered 'breaths/min'	(b) (4), (b) (6) System	27 Jan 2021 18:30:17



US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '126'	(b) (4), (b) (6)	27 Jan 2021 18:30:17

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered 'mmHg'	(b) (4), (b) (6) System	27 Jan 2021 18:30:17

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '79'	(b) (4), (b) (6)	27 Jan 2021 18:30:17

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered 'mmHg'	(b) (4), (b) (6) System	27 Jan 2021 18:30:17

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:57:09**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Jan 2021 18:30:17

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:57:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Jan 2021 18:30:17

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:57:09**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User entered empty.	System	27 Jan 2021 18:30:17
DataPoint set to visible.	System	27 Jan 2021 18:28:49

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	27 Jan 2021 18:30:17



US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:30:17

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '26 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 18:30:17

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '17:00'	(b) (4), (b) (6)	27 Jan 2021 18:30:17

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered '26 Jan 2021 17:00'	(b) (4), (b) (6) System	27 Jan 2021 18:30:17

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '36.6' C	(b) (4), (b) (6)	27 Jan 2021 18:30:17

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	27 Jan 2021 18:30:17

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:30:17

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '77'	(b) (4), (b) (6)	27 Jan 2021 18:30:17



**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered 'bpm'	(b) (4), (b) (6) System	27 Jan 2021 18:30:17

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '18'	(b) (4), (b) (6)	27 Jan 2021 18:30:17

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered 'breaths/min'	(b) (4), (b) (6) System	27 Jan 2021 18:30:17

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '125'	(b) (4), (b) (6)	27 Jan 2021 18:30:17

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered 'mmHg'	(b) (4), (b) (6) System	27 Jan 2021 18:30:17

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '75'	(b) (4), (b) (6)	27 Jan 2021 18:30:17

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered 'mmHg'	(b) (4), (b) (6) System	27 Jan 2021 18:30:17

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:57:09**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:30:23



US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:57:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	27 Jan 2021 18:30:28
User entered '26 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 18:30:28
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	27 Jan 2021 18:30:23
User entered '2 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 18:30:23

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:57:09

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:29:26

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '26 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 18:29:26

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Urine (URINE)'	(b) (4), (b) (6)	27 Jan 2021 18:29:26

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	27 Jan 2021 18:29:26

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	27 Jan 2021 18:29:26

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:29:26

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:29:26



**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered empty.	(b) (4), (b) (6) System	27 Jan 2021 18:29:26

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:30:39

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:30:39

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 18:30:39

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered 'mRNA-1273'	(b) (4), (b) (6)	
	System	27 Jan 2021 18:30:39
DataPoint set to visible.	System	27 Jan 2021 18:28:49

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '26 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 18:30:39

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '16:27'	(b) (4), (b) (6)	27 Jan 2021 18:30:39

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:57:09**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered '26 Jan 2021 16:27'	(b) (4), (b) (6) System	27 Jan 2021 18:30:39



US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	27 Jan 2021 18:30:39

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered 'ONCE'	(b) (4), (b) (6) System	27 Jan 2021 18:30:39

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	27 Jan 2021 18:30:39

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:57:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:28:59

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:57:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '26 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 18:28:59

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:09**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '15:42'	(b) (4), (b) (6)	27 Jan 2021 18:28:59

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:57:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered '26 Jan 2021 15:42'	(b) (4), (b) (6) System	27 Jan 2021 18:28:59

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:57:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:29:06



**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:57:09**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '26 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 18:29:06

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:57:09**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '15:51'	(b) (4), (b) (6)	27 Jan 2021 18:29:06

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:57:09**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered '26 Jan 2021 15:51'	(b) (4), (b) (6) System	27 Jan 2021 18:29:06

US3022233

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:57:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 18:31:28

**US3022233**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:09:42
User entered '1'	(b) (4), (b) (6) System	27 Jan 2021 18:31:28

**US3022233**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:06:45
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	02 Feb 2021 20:16:11

**US3022233**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:06:45
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User entered '02 Feb 2021'	Chevon Roberts (b) (4)	02 Feb 2021 20:16:11

**US3022233**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:06:45
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User entered 'Contact Made (CONTACT MADE)'	Chevon Roberts (b) (4)	02 Feb 2021 20:16:11



**US3022233**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:06:45
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User entered empty.	Chevon Roberts (b) (4)	02 Feb 2021 20:16:11

**US3022233**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:06:45
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:21:14
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	02 Feb 2021 20:16:17

**US3022233**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:06:45
User entered 'I'	System	02 Feb 2021 20:16:17

**US3022233**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:06:45
User entered 'I'	System	02 Feb 2021 20:16:17
DataPoint set to visible.	System	02 Feb 2021 20:16:17

**US3022233**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 17:24:50

**US3022233**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '09 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 17:24:50

US3022233

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:57:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:24:50

**US3022233**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:57:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User entered 'OLD29'	System	10 Mar 2021 17:24:50



**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 17:25:45

US3022233

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '14:23'	(b) (4), (b) (6)	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User entered '09 Mar 2021 14:23'	System	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '36.6' C	(b) (4), (b) (6)	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:25:45



**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '93'	(b) (4), (b) (6)	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User entered 'bpm'	System	10 Mar 2021 17:25:45

US3022233

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:57:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '17'	(b) (4), (b) (6)	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User entered 'breaths/min'	System	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '103'	(b) (4), (b) (6)	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User entered 'mmHg'	System	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '69'	(b) (4), (b) (6)	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User entered 'mmHg'	System	10 Mar 2021 17:25:45



US3022233

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '15:20'	(b) (4), (b) (6)	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User entered '09 Mar 2021 15:20'	System	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '36.4' C	(b) (4), (b) (6)	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:25:45



**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '82'	(b) (4), (b) (6)	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User entered 'bpm'	System	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '15'	(b) (4), (b) (6)	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User entered 'breaths/min'	System	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '123'	(b) (4), (b) (6)	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User entered 'mmHg'	System	10 Mar 2021 17:25:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '74'	(b) (4), (b) (6)	10 Mar 2021 17:25:45

US3022233

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:57:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User entered 'mmHg'	System	10 Mar 2021 17:25:45



**US3022233**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:57:09**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:25:57

**US3022233**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:57:09**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:25:57

**US3022233**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 17:26:16

**US3022233**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '09 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 17:26:16

**US3022233**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Urine (URINE)'	(b) (4), (b) (6)	10 Mar 2021 17:26:16

**US3022233**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:26:16

**US3022233**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 17:26:16

**US3022233**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:26:16



**US3022233**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:26:16

**US3022233**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:57:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User entered empty.	System	10 Mar 2021 17:26:16

**US3022233**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:57:09**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:26:32

**US3022233**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:57:09**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:26:32

US3022233

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:26:32

**US3022233**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:57:09**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User entered 'mRNA-1273'	System	10 Mar 2021 17:26:32
DataPoint set to visible.	System	02 Feb 2021 20:16:17

**US3022233**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:57:09**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:26:32

**US3022233**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:57:09**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '14:50'	(b) (4), (b) (6)	10 Mar 2021 17:26:32



**US3022233**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:57:09**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User entered '09 Mar 2021 14:50'	System	10 Mar 2021 17:26:32

US3022233

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:26:32

US3022233

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User entered 'ONCE'	System	10 Mar 2021 17:26:32

US3022233

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:57:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User entered 'INTRAMUSCULAR'	System	10 Mar 2021 17:26:32

**US3022233**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 17:26:45

**US3022233**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:53
User entered 'I'	System	10 Mar 2021 17:26:45

**US3022233**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:06:45
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 17:00:04

**US3022233**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:06:45
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '17 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 17:00:04



**US3022233**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:06:45
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Mar 2021 17:00:04

**US3022233**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:57:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:06:45
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 17:00:04

**US3022233**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:06:45
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 17:00:11

**US3022233**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:57:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:06:45
User entered 'I'	System	17 Mar 2021 17:00:11

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 21:57:09**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:15:54
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	09 Nov 2020 17:48:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 17:56:59

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 21:57:09**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:01:50
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:23
User entered	System	15 Oct 2020 13:07:17
'USA-US051-2020-mRNA-1273-P301000008'		
User entered 'New'	(b) (4), (b) (6)	15 Oct 2020 13:07:17

US3022233

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:57:09

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 18:57:10
User closed query 'Per CDM: please consider updating term to COVID-19' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 04:45:11
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.	(b) (4), (b) (6)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 14:26:11
Query 'Per CDM: please consider updating term to COVID-19' answered with 'updated' (Site from DM).	(b) (4)	
Data point term sent to Coder	System	19 Nov 2020 14:25:15
DataPoint Un-verified.	Shanice Bennett (b) (4)	19 Nov 2020 14:24:58
	(b) (4)	
Coding entries removed.	Shanice Bennett (b) (4)	19 Nov 2020 14:24:58
	(b) (4)	
User entered 'COVID-19' reason for change: Data Entry Error	Shanice Bennett (b) (4)	19 Nov 2020 14:24:58
	(b) (4)	
User opened query 'Per CDM: please consider updating term to COVID-19' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:19:42
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:01:50
	(b) (4), (b) (6)	
User closed query 'PV Query: Since this is a confirmed diagnosis of symptomatic Covid-19, please confirm if the event term can be updated to 'Covid-19'.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 17:26:50
	(b) (4), (b) (6)	
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)	26 Oct 2020 19:25:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 19:25:49
	(b) (4)	
Data point term sent to Coder	System	26 Oct 2020 18:22:28
Query 'PV Query: Since this is a confirmed diagnosis of symptomatic Covid-19, please confirm if the event term can be updated to 'Covid-19'.' answered with 'updaed' (Site from Safety).	Shanice Bennett (b) (4)	26 Oct 2020 18:22:08
	(b) (4)	
Coding entries removed.	Shanice Bennett (b) (4)	26 Oct 2020 18:22:01
	(b) (4)	

US3022233

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:57:09

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'COVID-19 INFECTION' reason for change: Data Entry Error	Shanice Bennett (b) (4)	26 Oct 2020 18:22:01
User opened query 'PV Query: Since this is a confirmed diagnosis of symptomatic Covid-19, please confirm if the event term can be updated to 'Covid-19'.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 12:56:11
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 21:26:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 21:26:17
Data point term sent to Coder	System	14 Oct 2020 21:00:03
User entered 'COVID Infection'	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50



US3022233

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:57:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 18:57:12
User closed query 'Per MM, please confirm this event is not a medically attended adverse event' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 04:45:15
Query 'Per MM, please confirm this event is not a medically attended adverse event' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	19 Nov 2020 14:25:30
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	19 Nov 2020 14:24:58
	(b) (4)	
User opened query 'Per MM, please confirm this event is not a medically attended adverse event' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:58:21
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:01:50
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	14 Oct 2020 20:59:50
	(b) (4)	

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50

US3022233

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:57:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 01:28:59
User closed query 'Please confirm start date as symptoms began on 2Oct2020.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 01:28:55
Query 'Please confirm start date as symptoms began on 2Oct2020.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	09 Nov 2020 19:55:50
	(b) (4)	
User entered '02 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	09 Nov 2020 19:54:59
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 18:02:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:01:50
	(b) (4), (b) (6)	
User opened query 'Please confirm start date as symptoms began on 2Oct2020.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 18:00:44
User closed query 'PV Query: The subject test positive and was symptomatic on 09 Oct 2020. However, the onset date for the event was reported as 13 Oct 2020. Please clarify.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 17:27:07
	(b) (4), (b) (6)	
Query 'PV Query: The subject test positive and was symptomatic on 09 Oct 2020. However, the onset date for the event was reported as 13 Oct 2020. Please clarify.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4)	26 Oct 2020 18:22:48
	(b) (4)	
User entered '09 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	26 Oct 2020 18:22:41
	(b) (4)	
User opened query 'PV Query: The subject test positive and was symptomatic on 09 Oct 2020. However, the onset date for the event was reported as 13 Oct 2020. Please clarify.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 12:56:25
	(b) (4), (b) (6)	
User entered '13 Oct 2020'	Shanice Bennett (b) (4)	14 Oct 2020 20:59:50
	(b) (4)	

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered empty.	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 21:57:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 20:59:50

US3022233

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:57:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 18:57:16
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	19 Nov 2020 14:25:47
DataPoint Un-verified.	Shanice Bennett (b) (4)	19 Nov 2020 14:25:47
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	19 Nov 2020 14:25:47
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	19 Nov 2020 14:24:58
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	14 Oct 2020 20:59:50
	(b) (4)	

US3022233

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:57:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 18:57:18
User closed query 'PV Query: Please provide the event end date (per protocol, when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	21 Nov 2020 16:37:18
User entered '21 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	19 Nov 2020 14:28:07
	(b) (4)	
Query 'PV Query: Please provide the event end date (per protocol, when symptoms have resolved).' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4)	19 Nov 2020 14:25:41
	(b) (4)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	19 Nov 2020 14:24:58
	(b) (4)	
User entered '15 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	19 Nov 2020 14:24:58
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (per protocol, when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:43:16
Query 'Please provide the event end date (per protocol, when symptoms have resolved).' canceled (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:43:03
User opened query 'Please provide the event end date (per protocol, when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:39:24
User closed query 'PV Query: Please provide the event end date (per protocol, when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 17:51:26
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:52:16
Query 'PV Query: Please provide the event end date (per protocol, when symptoms have resolved).' answered with 'not yet' (Site from Safety).	Shanice Bennett (b) (4)	09 Nov 2020 19:55:57
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 18:02:04
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:01:50
User opened query 'PV Query: Please provide the event end date (per protocol, when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 15:07:45
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 22:36:02

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'this patient is still being followed until negative COVID test results' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 20:38:40
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 14:13:01
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 17:27:15
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'will update as applicable ' (Site from Safety).	Shanice Bennett (b) (4)	26 Oct 2020 18:23:14
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 12:56:54
User entered empty.	Shanice Bennett (b) (4)	14 Oct 2020 20:59:50

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 21:57:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered empty.	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 21:57:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 20:59:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:57:09

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 01:29:08
User closed query 'Please confirm. Per source mild.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 01:29:06
Query 'Please confirm. Per source mild.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	09 Nov 2020 19:56:05
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	09 Nov 2020 19:55:39
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 18:02:06
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:01:50
	(b) (4), (b) (6)	
User opened query 'Please confirm. Per source mild.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 18:00:58
	(b) (4), (b) (6)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Shanice Bennett (b) (4)	14 Oct 2020 20:59:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:57:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered '0'	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:57:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered '0'	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered '0'	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:57:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered empty.	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:57:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered empty.	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered empty.	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered empty.	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:57:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered '0'	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered '0'	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50

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Folder: Adverse Events

Form: Adverse Events (6)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered '0'	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50

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Folder: Adverse Events

Form: Adverse Events (6)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:57:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:57:09

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:01:50
User closed query 'PV Query: As the last dose of study drug was given on 24 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 17:27:33
Query 'PV Query: As the last dose of study drug was given on 24 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'vaccine 2 was given' (Site from Safety).	Shanice Bennett (b) (4)	26 Oct 2020 18:23:51
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	23 Oct 2020 16:12:09
	(b) (4)	
User opened query 'PV Query: As the last dose of study drug was given on 24 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 12:57:26
User entered 'None (NONE)'	Shanice Bennett (b) (4)	14 Oct 2020 20:59:50
	(b) (4)	

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Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:57:09

None

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 01:52:24
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	09 Nov 2020 19:55:39
User entered '0' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	09 Nov 2020 19:55:39
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered '1'	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:57:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	20 Nov 2020 04:48:13
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 14:25:52
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 10:01:03
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:29:17
User closed query 'Please confirm as Aleve was taken for fever/headache 2Oct-6Oct.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 01:29:14
Query 'Please confirm as Aleve was taken for fever/headache 2Oct-6Oct.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4) (b) (4)	09 Nov 2020 19:56:11
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	09 Nov 2020 19:55:39
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4)	09 Nov 2020 19:55:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:01:50
User opened query 'Please confirm as Aleve was taken for fever/headache 2Oct-6Oct.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 18:01:39
User entered '0'	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered '0'	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:57:09

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 18:57:23
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Nov 2020 16:37:25
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4)	19 Nov 2020 14:25:57
	(b) (4)	
DataPoint Un-verified.	Shanice Bennett (b) (4)	19 Nov 2020 14:24:58
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Shanice Bennett (b) (4)	19 Nov 2020 14:24:58
Data Entry Error	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 16:39:03
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 17:51:31
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'awaiting saliva testing ' (Site from Safety).	Shanice Bennett (b) (4)	09 Nov 2020 19:56:37
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:01:50
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 15:07:21

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[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 14:37:46
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'UNKNOWN' (Site from Safety).	Shanice Bennett (b) (4)	03 Nov 2020 21:13:35
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 14:12:34
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 17:27:42
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'will update as applicable ' (Site from Safety).	Shanice Bennett (b) (4)	26 Oct 2020 18:24:19
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 12:56:39
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Shanice Bennett (b) (4)	14 Oct 2020 20:59:50

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Folder: Adverse Events

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:01:50
User entered empty.	Shanice Bennett (b) (4) (b) (4)	14 Oct 2020 20:59:50



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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User closed query 'PV Query: Please provide any additional COVID-19 testing results.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:51:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 01:52:28
Query 'PV Query: Please provide any additional COVID-19 testing results.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	09 Nov 2020 19:57:00
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	09 Nov 2020 19:56:52
User entered 'none' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	09 Nov 2020 19:56:52
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:01:50
User opened query 'PV Query: Please provide any additional COVID-19 testing results.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 15:08:11
User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 17:27:57
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 17:27:52
Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' answered with 'unknown' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	26 Oct 2020 18:24:42
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'no treatment given' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	26 Oct 2020 18:24:33

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Generated On: 11 Aug 2021 21:57:09

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 12:57:39
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 12:57:12
User entered empty.	Shanice Bennett (b) (4)	14 Oct 2020 20:59:50

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 20:59:50

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 14:24:58
User entered '0'	System	14 Oct 2020 20:59:50

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 08:42:35

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Form: Adverse Events (7)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Dental and oral soft tissue infections, PT: Gingivitis, LLT: Gum infection - version MedDRA\\23.0.	Coder Import (b) (4)	08 Feb 2021 13:50:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Feb 2021 13:50:32
	(b) (4)	
Data point term sent to Coder	System	08 Feb 2021 13:49:38
User entered 'gum infection'	(b) (4), (b) (6)	08 Feb 2021 13:48:37

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 13:48:37

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	08 Feb 2021 13:48:37



**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '31 Jan 2021'	(b) (4), (b) (6)	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 13:48:37

US3022233

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 21:57:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
User entered empty.	(b) (4), (b) (6) System	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	10 Mar 2021 17:29:39
	(b) (4), (b) (6)	
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 17:29:39
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 13:48:37
	(b) (4), (b) (6)	

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	10 Mar 2021 17:29:39
	(b) (4), (b) (6)	
User entered '24 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 17:29:39
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 13:48:37
	(b) (4), (b) (6)	

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 13:48:37

US3022233

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 21:57:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
User entered empty.	(b) (4), (b) (6) System	08 Feb 2021 13:48:37



**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	08 Feb 2021 13:48:37

US3022233

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 21:57:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 13:48:37

US3022233

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 21:57:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 13:48:37



**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'None (NONE)'	(b) (4), (b) (6)	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	08 Feb 2021 13:48:37



**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	10 Mar 2021 17:29:39
	(b) (4), (b) (6)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:		10 Mar 2021 17:29:39
Data Entry Error		
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
User entered '0'	(b) (4), (b) (6) System	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:35
User entered '1'	(b) (4), (b) (6) System	08 Feb 2021 13:48:37

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 21:57:09**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 08:42:35



**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 08:42:42

US3022233

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 21:57:09

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Herpes zoster - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 17:31:58
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 17:31:58
	(b) (4)	
Data point term sent to Coder	System	10 Mar 2021 17:31:15
User entered 'herpes zoster'	(b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered '20 Feb 2021'	(b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:30:27

US3022233

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 21:57:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
User entered empty.	(b) (4), (b) (6) System	10 Mar 2021 17:30:27



**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered '02 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:30:27

US3022233

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 21:57:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
User entered empty.	(b) (4), (b) (6) System	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 17:30:27



**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:30:27

US3022233

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 21:57:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 17:30:27



**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:30:27



**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

**Serious Adverse Event Derived (CSA Programming Field Only)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
User entered '0'	(b) (4), (b) (6) System	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:42
User entered '1'	(b) (4), (b) (6) System	10 Mar 2021 17:30:27

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 21:57:09**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 08:42:42

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 08:42:47

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 21:57:09

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy cervical - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 00:51:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 00:51:41
	(b) (4)	
Data point term sent to Coder	System	10 Mar 2021 17:32:17
User entered 'posterior cervical lymphadenopathy'	(b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 17:31:29



**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '20 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:31:29

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 21:57:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User entered empty.	(b) (4), (b) (6) System	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:31:29

US3022233

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 21:57:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User entered empty.	(b) (4), (b) (6) System	10 Mar 2021 17:31:29



**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:31:29

US3022233

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 21:57:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:31:29



**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered 'None (NONE)'	(b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
	(b) (4)	
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 13:52:43
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 17:31:29



US3022233

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 11 Aug 2021 21:57:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'updated ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:15:26
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 13:52:57
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:52:43
User entered '1'	(b) (4), (b) (6)	19 Mar 2021 18:52:10
	(b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User entered '0'	(b) (4), (b) (6) System	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:42:47
User entered '1'	(b) (4), (b) (6) System	10 Mar 2021 17:31:29

**US3022233**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 11 Aug 2021 21:57:09**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 08:42:47



US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:57:09

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:15:54
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User closed query 'Per ETRTR: Please confirm no medication was dosed for COVID-19. Update AE COVID19 CRF and ConMeds page if applicable, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 01:32:24
Query 'Per ETRTR: Please confirm no medication was dosed for COVID-19. Update AE COVID19 CRF and ConMeds page if applicable, thanks.' answered with 'NO MEDICATION' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 22:45:50
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:57:02
User opened query 'Per ETRTR: Please confirm no medication was dosed for COVID-19. Update AE COVID19 CRF and ConMeds page if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	16 Oct 2020 18:46:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 17:55:51

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:57:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:40:12
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 14:26:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	19 Nov 2020 14:26:59
Data point term sent to Coder Coding entries removed.	System Shanice Bennett (b) (4)	19 Nov 2020 14:26:16 19 Nov 2020 14:25:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:57:18
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: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 23:54:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	08 Oct 2020 23:54:33
Data point term sent to Coder User entered 'aleve'	System (b) (4), (b) (6)	08 Oct 2020 17:56:54 08 Oct 2020 17:56:42

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:40:12
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:57:18
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 17:56:42

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:57:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:40:12
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Un-verified.	Shanice Bennett (b) (4)	19 Nov 2020 14:25:17
User entered 'COVID-19' reason for change: Data Entry Error	Shanice Bennett (b) (4)	19 Nov 2020 14:25:17
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:57:18
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:11:09
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:07:25
User entered 'Fever and Headache'	(b) (4), (b) (6)	08 Oct 2020 17:56:42

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:57:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:40:12
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4)	31 Jan 2021 03:43:39
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'this is correct dose' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 19:13:30
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 16:14:55
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:57:18
User entered '375'	(b) (4), (b) (6)	08 Oct 2020 17:56:42

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:40:12
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:57:18
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Oct 2020 17:56:42

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:40:12
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:57:18
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 17:56:42

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:40:12
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:57:18
User entered 'as needed (PRN)'	(b) (4), (b) (6)	08 Oct 2020 17:56:42



US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:57:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:40:12
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:57:18
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 17:56:42

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:40:12
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:57:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Oct 2020 17:56:42

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:40:12
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:57:18
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 17:56:42

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:40:12
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:57:18
User entered '02 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 17:56:42

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:40:12
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:57:18
User entered '0'	(b) (4), (b) (6)	08 Oct 2020 17:56:42

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:40:12
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:57:18
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 17:56:42

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:40:12
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:57:18
User entered '06 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 17:56:42

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:40:12
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:57:18
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 17:56:42



**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:40:12
User entered empty.	System	08 Oct 2020 17:56:42

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:40:12
User entered empty.	System	08 Oct 2020 17:56:42

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:40:12
User entered empty.	System	08 Oct 2020 17:56:42

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:57:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 20:18:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 20:18:32
Data point term sent to Coder	System	02 Feb 2021 20:17:44
User entered 'Amoxicillin'	Chevon Roberts (b) (4)	02 Feb 2021 20:17:02

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:57:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	02 Feb 2021 20:17:02
	(b) (4)	

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'Gum infection'	(b) (4) Chevon Roberts (b) (4)	02 Feb 2021 20:17:02

US3022233

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered '500'	(b) (4) Chevon Roberts (b) (4)	02 Feb 2021 20:17:02

US3022233

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'mg (mg)'	Chevon Roberts (b) (4)	02 Feb 2021 20:17:02
	(b) (4)	



US3022233

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:57:09**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered empty.	(b) (4) Chevon Roberts (b) (4)	02 Feb 2021 20:17:02
	(b) (4)	

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:57:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'four times daily (QID)'	(b) (4) Chevon Roberts (b) (4)	02 Feb 2021 20:17:02

US3022233

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:57:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered empty.	(b) (4) Chevon Roberts (b) (4)	02 Feb 2021 20:17:02
	(b) (4)	

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'Oral (ORAL)'	Chevon Roberts (b) (4)	02 Feb 2021 20:17:02

US3022233

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:57:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	02 Feb 2021 20:17:02
	(b) (4)	

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:57:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '31 Jan 2021'	Chevon Roberts (b) (4)	02 Feb 2021 20:17:02
	(b) (4)	

US3022233

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '0'	Chevon Roberts (b) (4)	02 Feb 2021 20:17:02
	(b) (4)	

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	02 Feb 2021 20:17:02
	(b) (4)	



US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:57:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	02 Feb 2021 20:17:02
	(b) (4)	

US3022233

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'No (N)'	(b) (4) Chevon Roberts (b) (4)	02 Feb 2021 20:17:02

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Feb 2021 20:17:02

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 20:17:02

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Feb 2021 20:17:02

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:57:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
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)	08 Feb 2021 13:53:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 13:53:32
Data point term sent to Coder	System	08 Feb 2021 13:52:39
User entered 'influenza vaccine'	(b) (4), (b) (6)	08 Feb 2021 13:51:46

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:57:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:37
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User closed query 'Per DM CLR: Indication reflect prophylaxis, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 01:08:07
Query 'Per DM CLR: Indication reflect prophylaxis, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 17:27:03
Signature has been broken.	(b) (4), (b) (6)	10 Mar 2021 17:26:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 17:26:58
User opened query 'Per DM CLR: Indication reflect prophylaxis, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Mar 2021 00:29:29
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'No (N)'	(b) (4), (b) (6)	08 Feb 2021 13:51:46

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:57:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'influenza prevention'	(b) (4), (b) (6)	08 Feb 2021 13:51:46



**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:57:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered '0.5'	(b) (4), (b) (6)	08 Feb 2021 13:51:46

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:57:09**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'mL (mL)'	(b) (4), (b) (6)	08 Feb 2021 13:51:46

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:57:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 13:51:46

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:57:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'once (ONCE)'	(b) (4), (b) (6)	08 Feb 2021 13:51:46

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:57:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 13:51:46

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:57:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	08 Feb 2021 13:51:46

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:57:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 13:51:46

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:57:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered '22 Dec 2020'	(b) (4), (b) (6)	08 Feb 2021 13:51:46



**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:57:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered '0'	(b) (4), (b) (6)	08 Feb 2021 13:51:46

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:57:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'No (N)'	(b) (4), (b) (6)	08 Feb 2021 13:51:46

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:57:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered '22 Dec 2020'	(b) (4), (b) (6)	08 Feb 2021 13:51:46

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:57:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:37
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
User entered 'No (N)'	(b) (4), (b) (6)	08 Feb 2021 13:51:46

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:57:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:37
User entered empty.	System	08 Feb 2021 13:51:46

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:57:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:37
User entered empty.	System	08 Feb 2021 13:51:46

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:57:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:37
User entered empty.	System	08 Feb 2021 13:51:46

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:57:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Mar 2021 17:28:55
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 Mar 2021 17:28:55
Data point term sent to Coder	System	10 Mar 2021 17:28:09
User entered 'amoxicillin'	(b) (4), (b) (6)	10 Mar 2021 17:27:56



US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:57:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:27:56

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:57:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:13:12
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'there is an ae listed for this' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 15:53:40
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 06:12:25
User entered 'gum infection'	(b) (4), (b) (6)	10 Mar 2021 17:27:56

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:57:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '500'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:27:56

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:57:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:27:56

US3022233

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:57:09**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:27:56

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:57:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'four times daily (QID)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:27:56

US3022233

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:57:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:27:56

US3022233

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:57:09**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:27:56



US3022233

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:57:09**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:27:56

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:57:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '31 Jan 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:27:56

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:57:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:27:56

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:57:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:27:56

US3022233

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:57:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:27:56

US3022233

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:57:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:27:56

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:57:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	10 Mar 2021 17:27:56

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:57:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Mar 2021 17:27:56



**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:57:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Mar 2021 17:27:56

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:57:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:42
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR, PRODUCTSYNONYM: VALACYCLOVIR [VALACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 17:29:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 17:29:54
Data point term sent to Coder	System	10 Mar 2021 17:29:12
User entered 'valacyclovir'	(b) (4), (b) (6)	10 Mar 2021 17:28:35

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:42
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 17:28:35

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:57:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:42
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 14:13:42
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'There is a ae listed for this' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 15:53:51
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 06:12:41
User entered 'herpes zoster'	(b) (4), (b) (6)	10 Mar 2021 17:28:35

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:42
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 17:28:35

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:09**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:42
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'g (g)'	(b) (4), (b) (6)	10 Mar 2021 17:28:35

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:42
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:28:35

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:57:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:42
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:28:35



**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:42
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:28:35

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:42
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Mar 2021 17:28:35

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:57:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:42
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:28:35

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:42
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '20 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 17:28:35

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:42
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 17:28:35

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:42
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 17:28:35

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:42
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '02 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 17:28:35

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:42
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 17:28:35



**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:42
User entered '3'	System	10 Mar 2021 17:28:35

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:42
User entered '1'	System	10 Mar 2021 17:28:35

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 21:57:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:42
User entered '804 (804)'	System	10 Mar 2021 17:28:35

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:57:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 10:57:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 10:57:43
Data point term sent to Coder	System	10 Mar 2021 17:29:13
User entered 'diclofenac'	(b) (4), (b) (6)	10 Mar 2021 17:29:10

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 17:29:10

US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:57:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:14:35
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'There is a ae listed for this' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 15:54:03
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 06:12:51
User entered 'herpes zoster'	(b) (4), (b) (6)	10 Mar 2021 17:29:10

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '75'	(b) (4), (b) (6)	10 Mar 2021 17:29:10

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Mar 2021 17:29:10



US3022233

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:57:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:29:10

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'twice daily (BID)'	(b) (4), (b) (6)	10 Mar 2021 17:29:10

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:29:10

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Mar 2021 17:29:10

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 17:29:10

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '20 Feb 2021'	(b) (4), (b) (6)	10 Mar 2021 17:29:10

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 17:29:10

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 17:29:10



**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered '02 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 17:29:10

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 17:29:10

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:44
User entered '2'	System	10 Mar 2021 17:29:10

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:44
User entered '1'	System	10 Mar 2021 17:29:10

**US3022233**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:29:44
User entered '804 (804)'	System	10 Mar 2021 17:29:10

US3022233

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 21:57:09**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:07
User entered 'No (N)'	(b) (4) Chevon Roberts (b) (4)	29 Mar 2021 13:54:04

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'USA-US051-2020-MRNA-1273-P301000008'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17



**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Paul'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Bradley'	System	15 Oct 2020 13:07:17



**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered '340 Eisenhower Dr.'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Savannah'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'GA'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered '31406'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 17:28:24
User entered 'US'	System	15 Oct 2020 13:07:57

US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 21:57:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '6'	System	21 Nov 2020 16:37:47
User entered '5'	System	10 Nov 2020 17:52:26
User entered '4'	System	04 Nov 2020 14:39:15
User entered '3'	System	03 Nov 2020 22:36:34
User entered '2'	System	27 Oct 2020 17:28:34
User entered '1'	System	15 Oct 2020 13:07:57

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'USA-US051-2020-MRNA-1273-P301000008'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17



**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Paul'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Bradley'	System	15 Oct 2020 13:07:17



**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered '340 Eisenhower Dr.'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Savannah'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'GA'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered '31406'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 17:28:24
User entered 'US'	System	15 Oct 2020 13:07:57

US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 21:57:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '6'	System	21 Nov 2020 16:37:47
User entered '5'	System	10 Nov 2020 17:52:26
User entered '4'	System	04 Nov 2020 14:39:15
User entered '3'	System	03 Nov 2020 22:36:34
User entered '2'	System	27 Oct 2020 17:28:34
User entered '1'	System	15 Oct 2020 13:07:57

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form (1)**

**Generated On: 11 Aug 2021 21:57:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
User entered '15/Oct/2020 13:07'	System	15 Oct 2020 13:07:57

US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:57:09

**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.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 17:28:24
User entered 'I'	(b) (4), (b) (6)	15 Oct 2020 13:07:57



**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'USA-US051-2020-MRNA-1273-P301000008'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17



US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 21:57:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Paul'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Bradley'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered '340 Eisenhower Dr.'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Savannah'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'GA'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered '31406'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 17:28:24
User entered 'US'	System	15 Oct 2020 13:07:57

US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 21:57:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '6'	System	21 Nov 2020 16:37:47
User entered '5'	System	10 Nov 2020 17:52:26
User entered '4'	System	04 Nov 2020 14:39:15
User entered '3'	System	03 Nov 2020 22:36:34
User entered '2'	System	27 Oct 2020 17:28:34
User entered '1'	System	15 Oct 2020 13:07:57



**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form (2)**

**Generated On: 11 Aug 2021 21:57:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
User entered '27/Oct/2020 17:28'	System	27 Oct 2020 17:28:34

US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:57:09

**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.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 22:36:22
User entered 'I'	(b) (4), (b) (6)	27 Oct 2020 17:28:34

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'USA-US051-2020-MRNA-1273-P301000008'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17



**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 21:57:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Paul'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Bradley'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered '340 Eisenhower Dr.'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Savannah'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'GA'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered '31406'	System	15 Oct 2020 13:07:17



**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 17:28:24
User entered 'US'	System	15 Oct 2020 13:07:57

US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 21:57:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '6'	System	21 Nov 2020 16:37:47
User entered '5'	System	10 Nov 2020 17:52:26
User entered '4'	System	04 Nov 2020 14:39:15
User entered '3'	System	03 Nov 2020 22:36:34
User entered '2'	System	27 Oct 2020 17:28:34
User entered '1'	System	15 Oct 2020 13:07:57

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form (3)**

**Generated On: 11 Aug 2021 21:57:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
User entered '03/Nov/2020 22:36'	System	03 Nov 2020 22:36:34

US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:57:09

**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.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 14:39:03
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 22:36:34

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'USA-US051-2020-MRNA-1273-P301000008'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17



**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Paul'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Bradley'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered '340 Eisenhower Dr.'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Savannah'	System	15 Oct 2020 13:07:17



**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'GA'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered '31406'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 17:28:24
User entered 'US'	System	15 Oct 2020 13:07:57

US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 21:57:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '6'	System	21 Nov 2020 16:37:47
User entered '5'	System	10 Nov 2020 17:52:26
User entered '4'	System	04 Nov 2020 14:39:15
User entered '3'	System	03 Nov 2020 22:36:34
User entered '2'	System	27 Oct 2020 17:28:34
User entered '1'	System	15 Oct 2020 13:07:57

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form (4)**

**Generated On: 11 Aug 2021 21:57:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
User entered '04/Nov/2020 14:39'	System	04 Nov 2020 14:39:15

US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 21:57:09

**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.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
User entered 'I'	(b) (4), (b) (6)	04 Nov 2020 14:39:15

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'USA-US051-2020-MRNA-1273-P301000008'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17



**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Paul'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Bradley'	System	15 Oct 2020 13:07:17



**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered '340 Eisenhower Dr.'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Savannah'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'GA'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered '31406'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 17:28:24
User entered 'US'	System	15 Oct 2020 13:07:57

US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 21:57:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '6'	System	21 Nov 2020 16:37:47
User entered '5'	System	10 Nov 2020 17:52:26
User entered '4'	System	04 Nov 2020 14:39:15
User entered '3'	System	03 Nov 2020 22:36:34
User entered '2'	System	27 Oct 2020 17:28:34
User entered '1'	System	15 Oct 2020 13:07:57

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form (5)**

**Generated On: 11 Aug 2021 21:57:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:57:03
User entered '10/Nov/2020 17:52'	System	10 Nov 2020 17:52:26

US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 21:57:09

**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.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 18:57:03
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 17:52:26



**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'USA-US051-2020-MRNA-1273-P301000008'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'No (N)'	System	15 Oct 2020 13:07:17



**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Paul'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Bradley'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered '340 Eisenhower Dr.'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'Savannah'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered 'GA'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:07:52
User entered '31406'	System	15 Oct 2020 13:07:17

**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 21:57:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:58:43
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 17:28:24
User entered 'US'	System	15 Oct 2020 13:07:57

US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 21:57:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
	(b) (4)	
User entered '6'	System	21 Nov 2020 16:37:47
User entered '5'	System	10 Nov 2020 17:52:26
User entered '4'	System	04 Nov 2020 14:39:15
User entered '3'	System	03 Nov 2020 22:36:34
User entered '2'	System	27 Oct 2020 17:28:34
User entered '1'	System	15 Oct 2020 13:07:57



**US3022233**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000008**

**Form: Safety Report Form (6)**

**Generated On: 11 Aug 2021 21:57:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:57:03
User entered '21/Nov/2020 11:37'	System	21 Nov 2020 16:37:47

US3022233

Folder: SAE USA-US051-2020-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 11 Aug 2021 21:57:09

**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.	Paul Bradley (b) (4)	24 Feb 2021 00:20:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 18:57:03
User entered 'I'	(b) (4), (b) (6)	21 Nov 2020 16:37:47