

US3672333 (Prod: Coastal Carolina Research Center)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:59:21

All time stamps listed in this document are displayed in GMT

US3672333

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 18:19:43

Generated On: 11 Aug 2021 22:59:21

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[Participant ID](#)

US3672333

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

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US3672333

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

Date of Birth (MMM yyyy)	(b) (6) 2000
Age	19
Age Units	YEARS
Age (Derived)	19
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

Date of Informed Consent ( <i>dd MMM yyyy</i> )	26 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) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

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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) 17 Feb 2021 21:01:06

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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) 17 Feb 2021 21:01:06

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Condition	ADHD ATTENTION DEFICIT HYPERACTIVITY DISORDER
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	16:33 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 16:33
Height (xxx.x)	161.5 cm
Weight (xxx.x)	77.9 kg
BMI (xxx.x)	29.86706 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) 17 Feb 2021 21:01:06

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 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) 17 Feb 2021 21:01:06

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Date of assessment (*dd MMM yyyy*) 26 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) 17 Feb 2021 21:01:06

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Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	26 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 21:01:06

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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) 17 Feb 2021 21:01:06

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 21:01:35

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Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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) 17 Feb 2021 21:01:35

Generated On: 11 Aug 2021 22:59:21

What was the date of randomization? (dd MMM yyyy) 26 AUG 2020

What was the participant's randomization number? 108965

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) 17 Feb 2021 21:01:35

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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) 17 Feb 2021 21:01:35

Generated On: 11 Aug 2021 22:59:21

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)	26 AUG 2020
Time of assessment (00:00-23:59)	16:33 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 16:33
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 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) 17 Feb 2021 21:01:35

Generated On: 11 Aug 2021 22:59:21

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)	26 AUG 2020
Time of assessment (00:00-23:59)	17:38 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 17:38
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 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: Physical Examination

Data signed: (b) (4) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

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) 17 Feb 2021 21:01:35

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Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

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

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

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

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) 26 AUG 2020

What was the treatment time? (00:00-23:59) 17:06 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 17:06

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) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 AUG 2020

Collection time (00:00-23:59)

16:52 (24 HR)

Collection date and time (derived)

26 AUG 2020 16:52

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:23	26 AUG 2020 16:23
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

**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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 17:42

PC Open Date & Time

26 AUG 2020 17:26

PC Close Date & Time

26 AUG 2020 19:56

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °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	26 AUG 2020 21:37
PC Open Date & Time	26 AUG 2020 20:51
PC Close Date & Time	27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:59:21

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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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 12:00

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:59:21

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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

98.3 °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

28 AUG 2020 13:07

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PC Open Date & Time

28 AUG 2020 12:00

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PC Close Date & Time

29 AUG 2020 11:59

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US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:59:21

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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

96.8 °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

29 AUG 2020 13:48

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PC Open Date & Time

29 AUG 2020 12:00

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PC Close Date & Time

30 AUG 2020 11:59

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US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:59:21

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.1 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

30 AUG 2020 12:01

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PC Open Date & Time

30 AUG 2020 12:00

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PC Close Date & Time

31 AUG 2020 11:59

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US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

31 AUG 2020 12:01

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:59:21

**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

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

01 SEP 2020 19:15

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 17:43

PC Open Date & Time

26 AUG 2020 17:26

PC Close Date & Time

26 AUG 2020 19:56

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

**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

26 AUG 2020 21:37

PC Open Date & Time

26 AUG 2020 20:51

PC Close Date & Time

27 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:59:21

**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

27 AUG 2020 12:01

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:59:21

**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

28 AUG 2020 13:08

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:59:21

**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

29 AUG 2020 13:48

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:59:21

**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

30 AUG 2020 12:01

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:59:21

**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

31 AUG 2020 12:02

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:59:21

**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

01 SEP 2020 19:16

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

**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 ☐

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 17:44
PC Open Date & Time	26 AUG 2020 17:26
PC Close Date & Time	26 AUG 2020 19:56

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

**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 ☐

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 21:38
PC Open Date & Time	26 AUG 2020 20:51
PC Close Date & Time	27 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:59:21

**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 ☒

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:59:21

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 12:01
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:59:21

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 13:08
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:59:21

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

49 of 2211

EAB) (1725)

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:59:21

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 13:48
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:59:21

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

51 of 2211

EAB) (1725)

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:59:21

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 12:01
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:59:21

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 ☒

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:59:21

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 12:02
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:59:21

**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 ☒

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:59:21

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 19:16
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

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 ☐

PC Time Stamp 03 SEP 2020 08:40

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3672333

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:59:21

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 SEP 2020 08:40
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3672333

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672333

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672333

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3672333

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 21:01:36

Generated On: 11 Aug 2021 22:59:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 21:01:36

Generated On: 11 Aug 2021 22:59:21

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)	23 SEP 2020
Time of assessment (00:00-23:59)	15:15 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 15:15
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 21:01:36

Generated On: 11 Aug 2021 22:59:21

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

US3672333

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 21:01:36

Generated On: 11 Aug 2021 22:59:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3672333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 17 Feb 2021 21:01:36

Generated On: 11 Aug 2021 22:59:21

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	23 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)	

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 21:01:35

Generated On: 11 Aug 2021 22:59:21

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 NO SWAB RESULT FOUND FROM DAY 1

What was the study treatment? \_\_\_\_\_

What was the treatment date? (dd MMM yyyy) \_\_\_\_\_

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

Treatment Date and Time (derived) \_\_\_\_\_

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

What was the frequency of the study treatment dosing? \_\_\_\_\_

What was the route of administration for the study treatment? \_\_\_\_\_

US3672333

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 21:01:35

Generated On: 11 Aug 2021 22:59:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 SEP 2020

Collection time (00:00-23:59)

15:30 (24 HR)

Collection date and time (derived)

23 SEP 2020 15:30

US3672333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 21:01:35

Generated On: 11 Aug 2021 22:59:21

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:30	23 SEP 2020 15:30
Nasopharyngeal Swab 2	No		

US3672333

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:01:35

Generated On: 11 Aug 2021 22:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

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

US3672333

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672333

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672333

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:01:06

Generated On: 11 Aug 2021 22:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 21:01:36

Generated On: 11 Aug 2021 22:59:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 21:01:36

Generated On: 11 Aug 2021 22:59:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	16:16 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 16:16
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672333

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 21:01:36

Generated On: 11 Aug 2021 22:59:21

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.*

US3672333

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 21:01:36

Generated On: 11 Aug 2021 22:59:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 OCT 2020
Collection time (00:00-23:59)	16:32 (24 HR)
Collection date and time (derived)	21 OCT 2020 16:32

US3672333

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:01:36

Generated On: 11 Aug 2021 22:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	26 OCT 2020 00:01:49
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**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

02 NOV 2020 00:01:30

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 12:01:06

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 00:01:51

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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	27 NOV 2020 00:01:17
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**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

04 DEC 2020 17:32:42

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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	11 DEC 2020 00:04:28
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**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

18 DEC 2020 00:01:40

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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	25 DEC 2020 21:35:55
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	01 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JAN 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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 <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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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 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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JAN 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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 <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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JAN 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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 <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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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 <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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**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

12 FEB 2021 13:48:57

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 20:58:23
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**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

26 FEB 2021 05:02:34

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 05:57:56
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 01:27:13
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 MAR 2021 10:04:15
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**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

26 MAR 2021 18:19:59

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 00:02:22

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 APR 2021 14:54:48
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 10:10:57

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 16:17:27

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**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

30 APR 2021 05:22:52

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**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 ☐

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2021 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

14 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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="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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Open Date & Time](#)

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04 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUN 2021 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Close Date & Time](#)

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22 JUN 2021 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

25 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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 <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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUL 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

23 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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="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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

30 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Open Date & Time](#)

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20 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 AUG 2021 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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 <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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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°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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	01 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 OCT 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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="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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Open Date & Time](#)

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05 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 NOV 2021 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	12 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 NOV 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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°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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

03 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 DEC 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	24 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 DEC 2021 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	07 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 JAN 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 509
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

14 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 523
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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="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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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 <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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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

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 ☐

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	18 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 FEB 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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

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 ☐

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Close Date & Time](#)

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01 MAR 2022 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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 <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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Open Date & Time](#)

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04 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**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 ☐

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Open Date & Time](#)

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11 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAR 2022 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**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 ☐

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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 <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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT

DAY 586

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

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

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

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

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

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

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**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 ☐

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Close Date & Time](#)

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12 APR 2022 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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="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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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03 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUN 2022 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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 ☐

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Open Date & Time](#)

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10 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUN 2022 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**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 ☐

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	08 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JUL 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Close Date & Time](#)

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30 AUG 2022 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	23 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 SEP 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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30 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 OCT 2022 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

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[Patient Cloud Open Date & Time](#)

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07 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 OCT 2022 23:59

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US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**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 ☐

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

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

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	21 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2022 23:59

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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"/>

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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28 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 NOV 2022 23:59

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US3672333

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:59:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		06 MAR 2021 05:58:13

US3672333

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:19:44

Generated On: 11 Aug 2021 22:59:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672333

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:19:44

Generated On: 11 Aug 2021 22:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:19:44

Generated On: 11 Aug 2021 22:59:21

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*

US3672333

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:19:44

Generated On: 11 Aug 2021 22:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:19:44

Generated On: 11 Aug 2021 22:59:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672333

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:19:44

Generated On: 11 Aug 2021 22:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 15:30:00

Generated On: 11 Aug 2021 22:59:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672333

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:19:44

Generated On: 11 Aug 2021 22:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 15:30:00

Generated On: 11 Aug 2021 22:59:21

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

Visit date (dd MMM yyyy)	12 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
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US3672333

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 15:30:00

Generated On: 11 Aug 2021 22:59:21

Were vital signs assessed? Yes ☐  
No ☒

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

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

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

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

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

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3672333

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 15:30:00

Generated On: 11 Aug 2021 22:59:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 MAR 2021

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

US3672333

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 15:30:00

Generated On: 11 Aug 2021 22:59:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 MAR 2021
Collection time (00:00-23:59)	14:14 (24 HR)
Collection date and time (derived)	12 MAR 2021 14:14

US3672333

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 15:30:00

Generated On: 11 Aug 2021 22:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 18:37:04

Generated On: 11 Aug 2021 22:59:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672333

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 18:37:04

Generated On: 11 Aug 2021 22:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3672333**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

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*

**US3672333**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:21**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: COVID-19 Contact

Data signed: (b) (4) 16 Apr 2021 15:29:58

Generated On: 11 Aug 2021 22:59:21

Date of Contact	24 MAR 2021
Time of Contact	13:45
Date and Time of Contact (derived)	24 MAR 2021 13:45
Type of Contact	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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"/>

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

	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 MAR 2021
------	-------------

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

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

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

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

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

Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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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US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

	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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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"/>

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

Symptom Day

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

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

	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 MAR 2021
------	-------------

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

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

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

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

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

Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 24 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

	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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 24 Mar 2021

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 24 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

Symptom Day

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

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

	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 MAR 2021
------	-------------

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

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

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

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

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

Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 24 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 24 Mar 2021

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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 24 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

	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 MAR 2021	
Assessment Not Done	False	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 24 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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 24 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

	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 MAR 2021	
Assessment Not Done	False	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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"/>

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

	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 24 Mar 2021

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

Symptom Day

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

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

Date	23 MAR 2021
------	-------------

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

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

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

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

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

Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 24 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

	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"/>

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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 24 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 MAR 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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 24 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 MAR 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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 24 Mar 2021

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

Date	26 MAR 2021
------	-------------

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

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

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

Temperature	98.7 F
-------------	--------

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

	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"/>

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

Symptom Day

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

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 MAR 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

Symptom Day

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

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 MAR 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	99.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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 24 Mar 2021

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 MAR 2021	
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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

Symptom Day

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

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 MAR 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 24 Mar 2021

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 24 Mar 2021

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Apr 2021 15:29:58

Generated On: 11 Aug 2021 22:59:21

Date of Visit	24 MAR 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	24 MAR 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Mar 2021 18:19:43

Generated On: 11 Aug 2021 22:59:21

Date of Contact	30 SEP 2020
Time of Contact	10:55
Date and Time of Contact (derived)	30 SEP 2020 10:55
Type of Contact	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 May 2021 15:34:38

Generated On: 11 Aug 2021 22:59:21

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"/>

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 May 2021 15:34:38

Generated On: 11 Aug 2021 22:59:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.5 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 30 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 May 2021 15:34:38

Generated On: 11 Aug 2021 22:59:21

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 May 2021 15:34:38

Generated On: 11 Aug 2021 22:59:21

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 30 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 03 May 2021 15:34:38

Generated On: 11 Aug 2021 22:59:21

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"/>

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 03 May 2021 15:34:38

Generated On: 11 Aug 2021 22:59:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	1 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 03 May 2021 15:34:38

Generated On: 11 Aug 2021 22:59:21

	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"/>

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 03 May 2021 15:34:38

Generated On: 11 Aug 2021 22:59:21

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 ☐

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 03 May 2021 15:34:38

Generated On: 11 Aug 2021 22:59:21

Symptom Day

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 03 May 2021 15:34:38

Generated On: 11 Aug 2021 22:59:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	2 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 03 May 2021 15:34:38

Generated On: 11 Aug 2021 22:59:21

	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"/>

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 03 May 2021 15:34:38

Generated On: 11 Aug 2021 22:59:21

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 ☐

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 03 May 2021 15:34:38

Generated On: 11 Aug 2021 22:59:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input 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 30 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 03 May 2021 15:34:38

Generated On: 11 Aug 2021 22:59:21

	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	
Assessment Not Done	
O2 Saturation	
O2 Saturation Units	
Temperature	

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

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

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

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

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 03 May 2021 15:34:38

Generated On: 11 Aug 2021 22:59:21

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

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 03 May 2021 15:34:38

Generated On: 11 Aug 2021 22:59:21

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

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Mar 2021 18:19:43

Generated On: 11 Aug 2021 22:59:21

Date of Visit	30 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	30 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 05 Mar 2021 18:19:43

Generated On: 11 Aug 2021 22:59:21

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	02 OCT 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

**US3672333**

**Folder: Illness Visit (2)**

**Form: Saliva Collection**

**Generated On: 11 Aug 2021 22:59:21**

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3672333

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 18:19:43

Generated On: 11 Aug 2021 22:59:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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	SICKD1

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 18:19:43

Generated On: 11 Aug 2021 22:59:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 10:55
Height (xxx.x)	160.0 cm
Weight (xxx.x)	78.7 kg
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672333

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 18:19:43

Generated On: 11 Aug 2021 22:59:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3672333

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 05 Mar 2021 18:19:43

Generated On: 11 Aug 2021 22:59:21

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

30 SEP 2020

US3672333

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

Visit date (dd MMM yyyy)	24 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	SICKD1
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US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 MAR 2021
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 13:50
Height (xxx.x)	161.5 cm
Weight (xxx.x)	77.5 kg
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 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)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672333

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

24 MAR 2021

---

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

---

US3672333

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

24 MAR 2021

US3672333

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 18:19:44

Generated On: 11 Aug 2021 22:59:21

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

Visit date (dd MMM yyyy)	12 FEB 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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US3672333

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 15:30:00

Generated On: 11 Aug 2021 22:59:21

Date of updated informed consent ( <i>dd MMM yyyy</i> )	12 FEB 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> )	12 FEB 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 type="radio"/> Not Administered <input checked="" 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

US3672333

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 18:19:44

Generated On: 11 Aug 2021 22:59:21

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

US3672333

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 18:19:44

Generated On: 11 Aug 2021 22:59:21

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)	12 FEB 2021
Time of assessment (00:00-23:59)	12:33 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 12:33
Temperature (xxx.x)	98.5 F
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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3672333

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 18:19:44

Generated On: 11 Aug 2021 22:59:21

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)	12 FEB 2021
Time of assessment (00:00-23:59)	13:41 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 13:41
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3672333

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

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 18:19:43

Generated On: 11 Aug 2021 22:59:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 FEB 2021

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

US3672333

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

Form: Pregnancy Test

Data signed: (b) (4) 05 Mar 2021 18:19:43

Generated On: 11 Aug 2021 22:59:21

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	12 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date	12 FEB 2021
Collection time	12:55
Collection date and time (derived)	12 FEB 2021 12:55

US3672333

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

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 18:19:43

Generated On: 11 Aug 2021 22:59:21

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) 12 FEB 2021

What was the treatment time? (00:00-23:59) 13:10 (24 HR)

Treatment Date and Time (derived) 12 FEB 2021 13:10

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

What was the frequency of the study treatment dosing? ONCE

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

US3672333

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 18:19:43

Generated On: 11 Aug 2021 22:59:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 FEB 2021

Collection time (00:00-23:59)

12:53 (24 HR)

Collection date and time (derived)

12 FEB 2021 12:53

US3672333

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 18:19:43

Generated On: 11 Aug 2021 22:59:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 FEB 2021
Collection time (00:00 - 23:59)	12:22
Collection Date and Time (derived)	12 FEB 2021 12:22

US3672333

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

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:19:43

Generated On: 11 Aug 2021 22:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:19:44

Generated On: 11 Aug 2021 22:59:21

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*

US3672333

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:19:44

Generated On: 11 Aug 2021 22:59:21

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

US3672333

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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

US3672333

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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)	12 MAR 2021
Time of assessment (00:00-23:59)	13:54 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 13:54
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3672333

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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)	12 MAR 2021
Time of assessment (00:00-23:59)	14:59 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 14:59
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	94 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3672333

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 MAR 2021

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

US3672333

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	12 MAR 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)	

US3672333

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

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) 12 MAR 2021

What was the treatment time? (00:00-23:59) 14:25 (24 HR)

Treatment Date and Time (derived) 12 MAR 2021 14:25

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

US3672333

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 15:29:59

Generated On: 11 Aug 2021 22:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 15:30:00

Generated On: 11 Aug 2021 22:59:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672333

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 15:30:00

Generated On: 11 Aug 2021 22:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672333

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 18:37:04

Generated On: 11 Aug 2021 22:59:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3672333

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 18:37:04

Generated On: 11 Aug 2021 22:59:21

Were vital signs assessed? Yes ☐  
No ☒

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

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

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

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

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

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3672333

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 18:37:04

Generated On: 11 Aug 2021 22:59:21

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.*

US3672333

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 18:37:04

Generated On: 11 Aug 2021 22:59:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 APR 2021
Collection time (00:00-23:59)	12:55 (24 HR)
Collection date and time (derived)	21 APR 2021 12:55

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 05 Mar 2021 18:19:44

Generated On: 11 Aug 2021 22:59:21

Visit Date	30 SEP 2020
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	True
Pregnancy Test	True

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 18:19:44

Generated On: 11 Aug 2021 22:59:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	15:15 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 15:15
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Pregnancy Test

Data signed: (b) (4) 05 Mar 2021 18:19:44

Generated On: 11 Aug 2021 22:59:21

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	30 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)	

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 15:30:00

Generated On: 11 Aug 2021 22:59:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 SEP 2020

Collection time (00:00-23:59)

15:35 (24 HR)

Collection date and time (derived)

30 SEP 2020 15:35

US3672333

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 18:19:43

Generated On: 11 Aug 2021 22:59:21

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 13:30:26

Generated On: 11 Aug 2021 22:59:21

AEID	
Adverse event	LYMPHADENOPATHY R UNDERARM (OPPOSITE)
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	7 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 SEP 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 (1)

Data signed: (b) (4) 19 Mar 2021 13:30:26

Generated On: 11 Aug 2021 22:59:21

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 type="radio"/> Related <input checked="" 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 13:30:26

Generated On: 11 Aug 2021 22:59:21

AEID

Adverse event

UPPER RESPIRATORY  
INFECTION  
(URI)

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) 24 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐  
No ☒

If not Ongoing, end date (dd MMM yyyy) 30 SEP 2020

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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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 13:30:26

Generated On: 11 Aug 2021 22:59:21

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

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 18:19:43

Generated On: 11 Aug 2021 22:59:21

---

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

Yes ☒

No ☐

---

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

---

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 21:47:02

Generated On: 11 Aug 2021 22:59:21

Name of Medication NEXPLANON

Prophylaxis Yes ☒  
No ☐

Indication CONTRACEPTION

Dose per administration 68

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 3 YEARS

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) 08 Apr 2021 21:47:02

Generated On: 11 Aug 2021 22:59:21

	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 checked="" type="radio"/>
If route of administration is Other, specify	SUBDERMAL	
Start date (dd MMM yyyy)	26 NOV 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 21:47:02

Generated On: 11 Aug 2021 22:59:21

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 21:47:02

Generated On: 11 Aug 2021 22:59:21

	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)		9 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		9 NOV 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"/>

US3672333

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 21:47:02

Generated On: 11 Aug 2021 22:59:21

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3672333

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 05 Mar 2021 18:19:43

Generated On: 11 Aug 2021 22:59:21

---

Date of dosing discontinuation (dd MMM yyyy) 23 SEP 2020

---

Primary reason for dosing discontinuation

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

---

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify AE#2

---

US3672333

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:59:21

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 ☐

Audit

US3672333 (Prod: Coastal Carolina Research Center)

**US3672333**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:59:21**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'US3672333'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 20:29:36

**US3672333**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 21:01:54

US3672333

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '26 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 20:29:37

US3672333

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:59:21

[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 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Aug 2020 21:01:54

**US3672333**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'SCRN'	System	26 Aug 2020 21:01:54

US3672333

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:21

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered (b) (6) 2000'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 20:29:38

**US3672333**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:21**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '19'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

**US3672333**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:21**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'YEARS'	System	28 Aug 2020 17:58:42

**US3672333**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:21**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered '19'	System	26 Aug 2020 21:02:06

**US3672333**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:21**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Female (F)'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

US3672333

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:21

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

**US3672333**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:21**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'I'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

**US3672333**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:21**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

**US3672333**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:21**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

US3672333

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

**US3672333**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:21**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

**US3672333**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:21**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

US3672333

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:21

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 17:58:42

**US3672333**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:59:21**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

US3672333

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:59:21

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:58:42

US3672333

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:21

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '26 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 21:02:06

US3672333

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'Aug 2020'	System	26 Aug 2020 21:02:06

**US3672333**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered '2020'	System	26 Aug 2020 21:02:06

US3672333

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:21

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	26 Aug 2020 21:02:06

US3672333

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 21:02:06

US3672333

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:59:21

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 21:02:06

**US3672333**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:59:21**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 21:02:06

**US3672333**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:59:21**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 21:02:06

**US3672333**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:59:21**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 20:29:37

**US3672333**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:59:21**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'I'	System	26 Aug 2020 21:02:10

US3672333

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 21:02:10

US3672333

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:59:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 17:58:51

US3672333

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit hyperactivity disorder - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 20:56:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 20:56:25
User closed query 'Per MM: please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 18:53:54
Data point term sent to Coder	System	21 Oct 2020 13:26:23
Query 'Per MM: please expand the abbreviation.' answered with 'Expanded per query.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 13:25:51
Coding entries removed.	(b) (4), (b) (6)	21 Oct 2020 13:25:42
User entered 'ADHD Attention Deficit Hyperactivity Disorder' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 13:25:42
User opened query 'Per MM: please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 20:00:36
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: ADHD - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:00:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:00:43
Data point term sent to Coder	System	28 Aug 2020 17:59:35
User entered 'ADHD'	(b) (4), (b) (6)	28 Aug 2020 17:59:04

**US3672333**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'un UNK 2006'	(b) (4), (b) (6)	28 Aug 2020 17:59:04

**US3672333**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:59:04

**US3672333**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 17:59:04

**US3672333**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 17:59:04

**US3672333**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:59:04

**US3672333**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'Jan 2006'	System	28 Aug 2020 17:59:04

US3672333

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered '2006'	System	28 Aug 2020 17:59:04

**US3672333**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered empty.	System	28 Aug 2020 17:59:04

**US3672333**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered empty.	System	28 Aug 2020 17:59:04

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 17:59:31

**US3672333**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '16:33'	(b) (4), (b) (6)	28 Aug 2020 17:59:31

**US3672333**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered '26 Aug 2020 16:33'	System	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '161.5' cm	(b) (4), (b) (6)	28 Aug 2020 17:59:31
DataPoint set to visible.	System	26 Aug 2020 21:02:10

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '77.9' kg	(b) (4) (b) (4), (b) (6)	28 Aug 2020 17:59:31
DataPoint set to visible.	System	26 Aug 2020 21:02:10

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered '29.86706'	System	28 Aug 2020 17:59:31
DataPoint set to visible.	System	26 Aug 2020 21:02:10

**US3672333**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'kg/m2'	System	28 Aug 2020 17:59:31
DataPoint set to visible.	System	26 Aug 2020 21:02:10

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Aug 2020 17:59:31

**US3672333**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'bpm'	System	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'breaths/min'	System	28 Aug 2020 17:59:31

**US3672333**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Aug 2020 17:59:31

**US3672333**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'mmHg'	System	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'mmHg'	System	28 Aug 2020 17:59:31

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14

US3672333

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14

US3672333

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:37:25

**US3672333**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '26 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 18:37:25

US3672333

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:37:33

US3672333

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:37:33

US3672333

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:37:33

US3672333

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:59:21

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:37:33

US3672333

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:37:33

**US3672333**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:59:21**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:37:33

**US3672333**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:37:33

US3672333

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:59:21

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:37:33

US3672333

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:21

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:37:44

**US3672333**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '26 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 18:37:44

**US3672333**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Urine (URINE)'	(b) (4), (b) (6)	28 Aug 2020 18:37:44

**US3672333**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	28 Aug 2020 18:37:44

**US3672333**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:37:44

**US3672333**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:37:44

**US3672333**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:37:44

**US3672333**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered empty.	System	28 Aug 2020 18:37:44

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'I'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'I'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

US3672333

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:59:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Resident in a community with ongoing person to person transmission.'	(b) (4), (b) (6)	28 Aug 2020 18:38:28

**US3672333**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:38:38

**US3672333**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:38:38

US3672333

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:38:38

**US3672333**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'VISIT1'	System	28 Aug 2020 18:38:38

US3672333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '26 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 20:49:28

US3672333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '108965'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 20:49:28

US3672333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 20:49:28

US3672333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:21

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)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:38:50

US3672333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:21

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)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:38:50

US3672333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:38:50

US3672333

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:59:21

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:50

**US3672333**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:59:21**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:38:50

**US3672333**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:47:23
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:08:35

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:40:25

**US3672333**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '16:33'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered '26 Aug 2020 16:33'	System	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '98.3' F	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '78'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'bpm'	System	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '13'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'breaths/min'	System	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '107'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'mmHg'	System	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '66'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'mmHg'	System	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Aug 2020 18:40:25

**US3672333**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:59:21**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '17:38'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered '26 Aug 2020 17:38'	System	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '98.9' F	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Oral (Oral)'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '91'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'bpm'	System	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '18'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'breaths/min'	System	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '103'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'mmHg'	System	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '66'	(b) (4), (b) (6)	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'mmHg'	System	28 Aug 2020 18:40:25

US3672333

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:40:30

**US3672333**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:40:30

US3672333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:21

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User closed query 'Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 08:11:14
Query 'Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 21:50:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:50:28
User opened query 'Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 06:17:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:40:40

US3672333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:21

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:50:28
User entered '26 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 18:40:40

US3672333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:21

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:50:28
User entered 'Urine (URINE)'	(b) (4), (b) (6)	28 Aug 2020 18:40:40

US3672333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:21

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:50:28
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	28 Aug 2020 18:40:40

US3672333

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:21

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:40:40

**US3672333**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:40:40

**US3672333**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:40:40

**US3672333**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered empty.	System	28 Aug 2020 18:40:40

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 21:40:25

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 21:40:25

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

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)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 21:40:25

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 21:40:25

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '26 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 21:40:25

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '17:06'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:40:25

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered '26 Aug 2020 17:06'	System	26 Aug 2020 21:40:25

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:40:25

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'ONCE'	System	26 Aug 2020 21:40:25

US3672333

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 21:40:25

US3672333

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:40:58

US3672333

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:40:58

US3672333

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '16:52'	(b) (4), (b) (6)	28 Aug 2020 18:40:58

**US3672333**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered '26 Aug 2020 16:52'	System	28 Aug 2020 18:40:58

US3672333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:59:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 26-AUG-2020 is recorded under Visit 1 Day 1 in EDC; however, swab sample is reported under "Unscheduled" visit in PPD portal. Please reconcile the correct visit and update if applicable, else clarify in site response if unscheduled kit was used.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 07:56:52
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 26-AUG-2020 is recorded under Visit 1 Day 1 in EDC; however, swab sample is reported under "Unscheduled" visit in PPD portal. Please reconcile the correct visit and update if applicable, else clarify in site response if unscheduled kit was used.' answered with 'listed correctly in my preclarus portal' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 12:26:17
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 26-AUG-2020 is recorded under Visit 1 Day 1 in EDC; however, swab sample is reported under "Unscheduled" visit in PPD portal. Please reconcile the correct visit and update if applicable, else clarify in site response if unscheduled kit was used.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 10:03:54
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '26 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 18:41:10

**US3672333**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 22:59:21**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	28 Aug 2020 18:41:10

US3672333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Re-query- Response noted and thank you. Would you please clarify to which visit the sample collected on 26-AUG-2020 belongs to ?' canceled (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:10:27
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Re-query- Response noted and thank you. Would you please clarify to which visit the sample collected on 26-AUG-2020 belongs to ?' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 03:29:26
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Sample dated 26AUG2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 03:26:01
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Sample dated 26AUG2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you' answered with 'we were waiting on a resupply of lab kits' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 16:57:18
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: Sample dated 26AUG2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:11:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:41:10

**US3672333**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '16:23'	(b) (4), (b) (6)	28 Aug 2020 18:41:10

**US3672333**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered '26 Aug 2020 16:23'	System	28 Aug 2020 18:41:10

**US3672333**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 22:59:21**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	28 Aug 2020 18:41:10

US3672333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:41:10

US3672333

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:59:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:41:10

**US3672333**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered empty.	System	28 Aug 2020 18:41:10

US3672333

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:41:15

**US3672333**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'I'	System	28 Aug 2020 18:41:15

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:42:49', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '7a278dfd-7ee6-4853-8d81-99e21f5d5564'	System	26 Aug 2020 21:43:06
User entered 'Yes (Y)'	System	26 Aug 2020 21:43:06

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:42:54', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '7a278dfd-7ee6-4853-8d81-99e21f5d5564' User entered '98.9'	System	26 Aug 2020 21:43:06
	System	26 Aug 2020 21:43:06

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:42:57', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '7a278dfd-7ee6-4853-8d81-99e21f5d5564'	System	26 Aug 2020 21:43:06
User entered 'No (N)'	System	26 Aug 2020 21:43:06

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:42:59', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '7a278dfd-7ee6-4853-8d81-99e21f5d5564' User entered '26 Aug 2020 17:42'	System	26 Aug 2020 21:43:06
	System	26 Aug 2020 21:43:06

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '26 Aug 2020 17:26'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '26 Aug 2020 19:56'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:27', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '69fcd28b-2c1c-4311-bd43-45f0a3d0afb5' User entered 'Yes (Y)'	System	27 Aug 2020 01:37:38
	System	27 Aug 2020 01:37:38

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:31', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '69fcd28b-2c1c-4311-bd43-45f0a3d0afb5' User entered '98.3'	System	27 Aug 2020 01:37:38
	System	27 Aug 2020 01:37:38

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:34', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '69fcd28b-2c1c-4311-bd43-45f0a3d0afb5'	System	27 Aug 2020 01:37:38
User entered 'No (N)'	System	27 Aug 2020 01:37:38

**US3672333**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:59:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:37', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '69fcd28b-2c1c-4311-bd43-45f0a3d0afb5' User entered '26 Aug 2020 21:37'	System	27 Aug 2020 01:37:38
	System	27 Aug 2020 01:37:38

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '26 Aug 2020 20:51'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 2'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:00:38', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'd092be52-780c-469d-8ef7-681d7283b797'	System	27 Aug 2020 16:00:54
User entered 'Yes (Y)'	System	27 Aug 2020 16:00:54

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:00:44', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'd092be52-780c-469d-8ef7-681d7283b797'	System	27 Aug 2020 16:00:54
User entered '97.9'	System	27 Aug 2020 16:00:54

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:00:46', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'd092be52-780c-469d-8ef7-681d7283b797'	System	27 Aug 2020 16:00:54
User entered 'No (N)'	System	27 Aug 2020 16:00:54

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:00:48', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'd092be52-780c-469d-8ef7-681d7283b797'	System	27 Aug 2020 16:00:54
User entered '27 Aug 2020 12:00'	System	27 Aug 2020 16:00:54

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 3'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:07:48', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '0141c041-cb40-4b63-aa55-0b4a7dd28679' User entered 'Yes (Y)'	System	28 Aug 2020 17:08:00
	System	28 Aug 2020 17:08:00

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:07:52', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '0141c041-cb40-4b63-aa55-0b4a7dd28679' User entered '98.3'	System	28 Aug 2020 17:08:00
	System	28 Aug 2020 17:08:00

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:07:54', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '0141c041-cb40-4b63-aa55-0b4a7dd28679' User entered 'No (N)'	System	28 Aug 2020 17:08:00
	System	28 Aug 2020 17:08:00

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:07:56', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '0141c041-cb40-4b63-aa55-0b4a7dd28679' User entered '28 Aug 2020 13:07'	System	28 Aug 2020 17:08:00
	System	28 Aug 2020 17:08:00

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 4'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:06', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'ad306163-e5f9-40e1-af8a-8ed7be4c01e7' User entered 'Yes (Y)'	System	29 Aug 2020 18:48:19
	System	29 Aug 2020 18:48:19

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:13', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'ad306163-e5f9-40e1-af8a-8ed7be4c01e7' User entered '96.8'	System	29 Aug 2020 18:48:19
	System	29 Aug 2020 18:48:19

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:15', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'ad306163-e5f9-40e1-af8a-8ed7be4c01e7'	System	29 Aug 2020 18:48:19
User entered 'No (N)'	System	29 Aug 2020 18:48:19

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:16', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'ad306163-e5f9-40e1-af8a-8ed7be4c01e7' User entered '29 Aug 2020 13:48'	System	29 Aug 2020 18:48:19
	System	29 Aug 2020 18:48:19

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 5'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:00:44', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '15e54e1a-c372-4fc9-8fb4-39f8f8a7d68a' User entered 'Yes (Y)'	System	30 Aug 2020 17:01:09
	System	30 Aug 2020 17:01:09

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:00:50', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '15e54e1a-c372-4fc9-8fb4-39f8f8a7d68a' User entered '98.1'	System	30 Aug 2020 17:01:09
	System	30 Aug 2020 17:01:09

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:00:56', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '15e54e1a-c372-4fc9-8fb4-39f8f8a7d68a' User entered 'No (N)'	System	30 Aug 2020 17:01:09
	System	30 Aug 2020 17:01:09

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '15e54e1a-c372-4fc9-8fb4-39f8f8a7d68a' User entered '30 Aug 2020 12:01'	System	30 Aug 2020 17:01:09
	System	30 Aug 2020 17:01:09

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 6'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:01:51', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'de3b2333-6911-4621-942b-90801609ddd2' User entered 'Yes (Y)'	System	31 Aug 2020 17:14:21
	System	31 Aug 2020 17:14:21

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:01:54', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'de3b2333-6911-4621-942b-90801609ddd2' User entered '98.6'	System	31 Aug 2020 17:14:21
	System	31 Aug 2020 17:14:21

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:01:56', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'de3b2333-6911-4621-942b-90801609ddd2'	System	31 Aug 2020 17:14:21
User entered 'No (N)'	System	31 Aug 2020 17:14:21

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:01:58', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'de3b2333-6911-4621-942b-90801609ddd2' User entered '31 Aug 2020 12:01'	System	31 Aug 2020 17:14:21
	System	31 Aug 2020 17:14:21

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 7'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:15:46', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '2c78903a-dac0-4f2f-b13f-64e565517bc6' User entered 'Yes (Y)'	System	01 Sep 2020 23:15:54
	System	01 Sep 2020 23:15:54

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:15:49', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '2c78903a-dac0-4f2f-b13f-64e565517bc6' User entered '96.2'	System	01 Sep 2020 23:15:54
	System	01 Sep 2020 23:15:54

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:15:51', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '2c78903a-dac0-4f2f-b13f-64e565517bc6'	System	01 Sep 2020 23:15:54
User entered 'No (N)'	System	01 Sep 2020 23:15:54

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:15:52', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '2c78903a-dac0-4f2f-b13f-64e565517bc6'	System	01 Sep 2020 23:15:54
User entered '01 Sep 2020 19:15'	System	01 Sep 2020 23:15:54

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:43:04', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '16109b97-da36-4350-a11f-98caea2c7b8f' User entered 'None (1)'	System	26 Aug 2020 21:43:54
	System	26 Aug 2020 21:43:54

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:43:06', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '16109b97-da36-4350-a11f-98caea2c7b8f' User entered 'No (N)'	System	26 Aug 2020 21:43:54
	System	26 Aug 2020 21:43:54

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:43:12', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '16109b97-da36-4350-a11f-98caea2c7b8f' User entered 'No (N)'	System	26 Aug 2020 21:43:54
	System	26 Aug 2020 21:43:54

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:43:15', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '16109b97-da36-4350-a11f-98caea2c7b8f' User entered 'None (1)'	System	26 Aug 2020 21:43:54
	System	26 Aug 2020 21:43:54

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:43:52', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '16109b97-da36-4350-a11f-98caea2c7b8f' User entered '26 Aug 2020 17:43'	System	26 Aug 2020 21:43:54
	System	26 Aug 2020 21:43:54

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '26 Aug 2020 17:26'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '26 Aug 2020 19:56'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:40', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '28ed5e38-070f-4b12-8165-5f553b06dde3' User entered 'None (1)'	System	27 Aug 2020 01:37:56
	System	27 Aug 2020 01:37:56

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:42', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '28ed5e38-070f-4b12-8165-5f553b06dde3' User entered 'No (N)'	System	27 Aug 2020 01:37:56
	System	27 Aug 2020 01:37:56

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:43', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '28ed5e38-070f-4b12-8165-5f553b06dde3' User entered 'No (N)'	System	27 Aug 2020 01:37:56
	System	27 Aug 2020 01:37:56

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:52', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '28ed5e38-070f-4b12-8165-5f553b06dde3' User entered 'None (1)'	System	27 Aug 2020 01:37:56
	System	27 Aug 2020 01:37:56

**US3672333**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:59:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:55', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '28ed5e38-070f-4b12-8165-5f553b06dde3' User entered '26 Aug 2020 21:37'	System	27 Aug 2020 01:37:56
	System	27 Aug 2020 01:37:56

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '26 Aug 2020 20:51'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 2'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:00:55', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'cfcfd9c3-3c2b-467b-a0a1-b1f3f9de4144'	System	27 Aug 2020 16:01:21
User entered 'None (1)'	System	27 Aug 2020 16:01:21

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:00:57', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'cfcfd9c3-3c2b-467b-a0a1-b1f3f9de4144'	System	27 Aug 2020 16:01:21
User entered 'No (N)'	System	27 Aug 2020 16:01:21

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:04', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'cfcfd9c3-3c2b-467b-a0a1-b1f3f9de4144'	System	27 Aug 2020 16:01:21
User entered 'No (N)'	System	27 Aug 2020 16:01:21

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:07', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'cfcfd9c3-3c2b-467b-a0a1-b1f3f9de4144'	System	27 Aug 2020 16:01:21
User entered 'None (1)'	System	27 Aug 2020 16:01:21

**US3672333**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:59:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:09', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'cfcfd9c3-3c2b-467b-a0a1-b1f3f9de4144' User entered '27 Aug 2020 12:01'	System	27 Aug 2020 16:01:21
	System	27 Aug 2020 16:01:21

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 3'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:07:59', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4e0f4cec-1990-425b-ae08-a47255b48652'	System	28 Aug 2020 17:08:11
User entered 'None (1)'	System	28 Aug 2020 17:08:11

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4e0f4cec-1990-425b-ae08-a47255b48652' User entered 'No (N)'	System	28 Aug 2020 17:08:11
	System	28 Aug 2020 17:08:11

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:01', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4e0f4cec-1990-425b-ae08-a47255b48652' User entered 'No (N)'	System	28 Aug 2020 17:08:11
	System	28 Aug 2020 17:08:11

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:03', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4e0f4cec-1990-425b-ae08-a47255b48652' User entered 'None (1)'	System	28 Aug 2020 17:08:11
	System	28 Aug 2020 17:08:11

**US3672333**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:59:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:06', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4e0f4cec-1990-425b-ae08-a47255b48652' User entered '28 Aug 2020 13:08'	System	28 Aug 2020 17:08:11
	System	28 Aug 2020 17:08:11

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 4'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:19', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'eb35ac98-7eb2-4022-81d9-7275a67cb061'	System	29 Aug 2020 18:48:28
User entered 'None (1)'	System	29 Aug 2020 18:48:28

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:21', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'eb35ac98-7eb2-4022-81d9-7275a67cb061' User entered 'No (N)'	System	29 Aug 2020 18:48:28
	System	29 Aug 2020 18:48:28

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:23', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'eb35ac98-7eb2-4022-81d9-7275a67cb061' User entered 'No (N)'	System	29 Aug 2020 18:48:28
	System	29 Aug 2020 18:48:28

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:24', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'eb35ac98-7eb2-4022-81d9-7275a67cb061'	System	29 Aug 2020 18:48:28
User entered 'None (1)'	System	29 Aug 2020 18:48:28

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:26', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'eb35ac98-7eb2-4022-81d9-7275a67cb061' User entered '29 Aug 2020 13:48'	System	29 Aug 2020 18:48:28
	System	29 Aug 2020 18:48:28

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 5'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:05', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'b0130488-f0eb-4709-8823-e12fa8bdbd3a' User entered 'None (1)'	System	30 Aug 2020 17:01:22
	System	30 Aug 2020 17:01:22

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:13', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'b0130488-f0eb-4709-8823-e12fa8bdbd3a' User entered 'No (N)'	System	30 Aug 2020 17:01:22
	System	30 Aug 2020 17:01:22

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:14', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'b0130488-f0eb-4709-8823-e12fa8bdbd3a' User entered 'No (N)'	System	30 Aug 2020 17:01:22
	System	30 Aug 2020 17:01:22

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:15', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'b0130488-f0eb-4709-8823-e12fa8bdbd3a' User entered 'None (1)'	System	30 Aug 2020 17:01:22
	System	30 Aug 2020 17:01:22

**US3672333**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:59:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:17', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'b0130488-f0eb-4709-8823-e12fa8bdbd3a' User entered '30 Aug 2020 12:01'	System	30 Aug 2020 17:01:22
	System	30 Aug 2020 17:01:22

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 6'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '67ef119c-2734-4d2f-9aea-80bfc946d201' User entered 'None (1)'	System	31 Aug 2020 17:14:24
	System	31 Aug 2020 17:14:24

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:02', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '67ef119c-2734-4d2f-9aea-80bfc946d201' User entered 'No (N)'	System	31 Aug 2020 17:14:24
	System	31 Aug 2020 17:14:24

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:03', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '67ef119c-2734-4d2f-9aea-80bfc946d201' User entered 'No (N)'	System	31 Aug 2020 17:14:24
	System	31 Aug 2020 17:14:24

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:04', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '67ef119c-2734-4d2f-9aea-80bfc946d201' User entered 'None (1)'	System	31 Aug 2020 17:14:24
	System	31 Aug 2020 17:14:24

**US3672333**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:59:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:06', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '67ef119c-2734-4d2f-9aea-80bfc946d201' User entered '31 Aug 2020 12:02'	System	31 Aug 2020 17:14:24
	System	31 Aug 2020 17:14:24

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 7'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:15:54', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '47de99dc-dddb-45de-9715-7b15e78829a3'	System	01 Sep 2020 23:16:01
User entered 'None (1)'	System	01 Sep 2020 23:16:01

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:15:56', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '47de99dc-dddb-45de-9715-7b15e78829a3'	System	01 Sep 2020 23:16:01
User entered 'No (N)'	System	01 Sep 2020 23:16:01

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:15:57', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '47de99dc-dddb-45de-9715-7b15e78829a3'	System	01 Sep 2020 23:16:01
User entered 'No (N)'	System	01 Sep 2020 23:16:01

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:15:58', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '47de99dc-dddb-45de-9715-7b15e78829a3'	System	01 Sep 2020 23:16:01
User entered 'None (1)'	System	01 Sep 2020 23:16:01

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:16:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '47de99dc-dddb-45de-9715-7b15e78829a3'	System	01 Sep 2020 23:16:01
User entered '01 Sep 2020 19:16'	System	01 Sep 2020 23:16:01

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:43:59', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '5563ee68-2ec3-461c-ada0-c35acf56463a' User entered 'None (0)'	System	26 Aug 2020 21:44:20
	System	26 Aug 2020 21:44:20

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:44:01', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '5563ee68-2ec3-461c-ada0-c35acf56463a' User entered 'None (0)'	System	26 Aug 2020 21:44:20
	System	26 Aug 2020 21:44:20

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:44:03', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '5563ee68-2ec3-461c-ada0-c35acf56463a' User entered 'None (0)'	System	26 Aug 2020 21:44:20
	System	26 Aug 2020 21:44:20

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:44:06', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '5563ee68-2ec3-461c-ada0-c35acf56463a' User entered 'None (0)'	System	26 Aug 2020 21:44:20
	System	26 Aug 2020 21:44:20

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:44:08', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '5563ee68-2ec3-461c-ada0-c35acf56463a' User entered 'None (0)'	System	26 Aug 2020 21:44:20
	System	26 Aug 2020 21:44:20

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:44:10', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '5563ee68-2ec3-461c-ada0-c35acf56463a' User entered 'None (0)'	System	26 Aug 2020 21:44:20
	System	26 Aug 2020 21:44:20

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:44:16', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '5563ee68-2ec3-461c-ada0-c35acf56463a' User entered 'No (N)'	System	26 Aug 2020 21:44:20
	System	26 Aug 2020 21:44:20

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T17:44:17', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '5563ee68-2ec3-461c-ada0-c35acf56463a' User entered '26 Aug 2020 17:44'	System	26 Aug 2020 21:44:20
	System	26 Aug 2020 21:44:20

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '26 Aug 2020 17:26'	System	26 Aug 2020 21:40:25

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '26 Aug 2020 19:56'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:57', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a2455866-501c-420b-a337-09c1a3aca32b' User entered 'None (0)'	System	27 Aug 2020 01:38:15
	System	27 Aug 2020 01:38:15

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:37:59', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a2455866-501c-420b-a337-09c1a3aca32b' User entered 'None (0)'	System	27 Aug 2020 01:38:15
	System	27 Aug 2020 01:38:15

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:38:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a2455866-501c-420b-a337-09c1a3aca32b' User entered 'None (0)'	System	27 Aug 2020 01:38:15
	System	27 Aug 2020 01:38:15

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:38:01', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a2455866-501c-420b-a337-09c1a3aca32b' User entered 'None (0)'	System	27 Aug 2020 01:38:15
	System	27 Aug 2020 01:38:15

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:38:02', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a2455866-501c-420b-a337-09c1a3aca32b' User entered 'None (0)'	System	27 Aug 2020 01:38:15
	System	27 Aug 2020 01:38:15

**US3672333**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:59:21**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:38:04', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a2455866-501c-420b-a337-09c1a3aca32b' User entered 'None (0)'	System	27 Aug 2020 01:38:15
	System	27 Aug 2020 01:38:15

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:38:08', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a2455866-501c-420b-a337-09c1a3aca32b' User entered 'No (N)'	System	27 Aug 2020 01:38:15
	System	27 Aug 2020 01:38:15

**US3672333**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:59:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-26T21:38:10', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a2455866-501c-420b-a337-09c1a3aca32b' User entered '26 Aug 2020 21:38'	System	27 Aug 2020 01:38:15
	System	27 Aug 2020 01:38:15

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '26 Aug 2020 20:51'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 2'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:59:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:12', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'e153d150-70dd-4a28-9610-67b8cfc5ee5c' User entered 'None (0)'	System	27 Aug 2020 16:01:42
	System	27 Aug 2020 16:01:42

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:59:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:13', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'e153d150-70dd-4a28-9610-67b8cfc5ee5c' User entered 'None (0)'	System	27 Aug 2020 16:01:42
	System	27 Aug 2020 16:01:42

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:59:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:14', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'e153d150-70dd-4a28-9610-67b8cfc5ee5c' User entered 'None (0)'	System	27 Aug 2020 16:01:42
	System	27 Aug 2020 16:01:42

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:59:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:18', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'e153d150-70dd-4a28-9610-67b8cfc5ee5c'	System	27 Aug 2020 16:01:42
User entered 'No interference with activity (1)'	System	27 Aug 2020 16:01:42

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:20', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'e153d150-70dd-4a28-9610-67b8cfc5ee5c' User entered 'None (0)'	System	27 Aug 2020 16:01:42
	System	27 Aug 2020 16:01:42

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:22', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'e153d150-70dd-4a28-9610-67b8cfc5ee5c' User entered 'No interference with activity (1)'	System	27 Aug 2020 16:01:42
	System	27 Aug 2020 16:01:42

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:25', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'e153d150-70dd-4a28-9610-67b8cfc5ee5c' User entered 'No (N)'	System	27 Aug 2020 16:01:42
	System	27 Aug 2020 16:01:42

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-27T12:01:27', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'e153d150-70dd-4a28-9610-67b8cfc5ee5c' User entered '27 Aug 2020 12:01'	System	27 Aug 2020 16:01:42
	System	27 Aug 2020 16:01:42

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 3'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:59:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:10', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4b6caea7-da22-42f9-bfab-b449874c1313' User entered 'None (0)'	System	28 Aug 2020 17:08:37
	System	28 Aug 2020 17:08:37

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:59:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:12', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4b6caea7-da22-42f9-bfab-b449874c1313' User entered 'None (0)'	System	28 Aug 2020 17:08:37
	System	28 Aug 2020 17:08:37

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:59:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:13', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4b6caea7-da22-42f9-bfab-b449874c1313' User entered 'None (0)'	System	28 Aug 2020 17:08:37
	System	28 Aug 2020 17:08:37

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:59:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:15', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4b6caea7-da22-42f9-bfab-b449874c1313' User entered 'None (0)'	System	28 Aug 2020 17:08:37
	System	28 Aug 2020 17:08:37

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:59:21

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:26', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4b6caea7-da22-42f9-bfab-b449874c1313' User entered 'None (0)'	System	28 Aug 2020 17:08:37
	System	28 Aug 2020 17:08:37

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:59:21

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:29', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4b6caea7-da22-42f9-bfab-b449874c1313' User entered 'None (0)'	System	28 Aug 2020 17:08:37
	System	28 Aug 2020 17:08:37

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:31', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4b6caea7-da22-42f9-bfab-b449874c1313' User entered 'No (N)'	System	28 Aug 2020 17:08:37
	System	28 Aug 2020 17:08:37

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-28T13:08:33', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '4b6caea7-da22-42f9-bfab-b449874c1313' User entered '28 Aug 2020 13:08'	System	28 Aug 2020 17:08:37
	System	28 Aug 2020 17:08:37

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 4'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:59:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:28', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '606dfa27-4a00-422a-911e-d940ef350be3' User entered 'None (0)'	System	29 Aug 2020 18:48:48
	System	29 Aug 2020 18:48:48

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:59:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:30', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '606dfa27-4a00-422a-911e-d940ef350be3' User entered 'None (0)'	System	29 Aug 2020 18:48:48
	System	29 Aug 2020 18:48:48

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:59:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:31', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '606dfa27-4a00-422a-911e-d940ef350be3' User entered 'None (0)'	System	29 Aug 2020 18:48:48
	System	29 Aug 2020 18:48:48

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:59:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:33', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '606dfa27-4a00-422a-911e-d940ef350be3' User entered 'None (0)'	System	29 Aug 2020 18:48:48
	System	29 Aug 2020 18:48:48

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:59:21

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:34', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '606dfa27-4a00-422a-911e-d940ef350be3' User entered 'None (0)'	System	29 Aug 2020 18:48:48
	System	29 Aug 2020 18:48:48

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:59:21

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:35', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '606dfa27-4a00-422a-911e-d940ef350be3' User entered 'None (0)'	System	29 Aug 2020 18:48:48
	System	29 Aug 2020 18:48:48

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:37', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '606dfa27-4a00-422a-911e-d940ef350be3' User entered 'No (N)'	System	29 Aug 2020 18:48:48
	System	29 Aug 2020 18:48:48

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-29T13:48:45', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '606dfa27-4a00-422a-911e-d940ef350be3' User entered '29 Aug 2020 13:48'	System	29 Aug 2020 18:48:48
	System	29 Aug 2020 18:48:48

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 5'	System	26 Aug 2020 21:40:25

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:19', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'c310b51e-83fa-4e5d-817a-850db23826a1' User entered 'None (0)'	System	30 Aug 2020 17:01:48
	System	30 Aug 2020 17:01:48

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:59:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:21', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'c310b51e-83fa-4e5d-817a-850db23826a1' User entered 'None (0)'	System	30 Aug 2020 17:01:48
	System	30 Aug 2020 17:01:48

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:59:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:36', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'c310b51e-83fa-4e5d-817a-850db23826a1' User entered 'None (0)'	System	30 Aug 2020 17:01:48
	System	30 Aug 2020 17:01:48

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:59:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:38', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'c310b51e-83fa-4e5d-817a-850db23826a1' User entered 'None (0)'	System	30 Aug 2020 17:01:48
	System	30 Aug 2020 17:01:48

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:59:21

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:39', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'c310b51e-83fa-4e5d-817a-850db23826a1' User entered 'None (0)'	System	30 Aug 2020 17:01:48
	System	30 Aug 2020 17:01:48

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:40', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'c310b51e-83fa-4e5d-817a-850db23826a1' User entered 'None (0)'	System	30 Aug 2020 17:01:48
	System	30 Aug 2020 17:01:48

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:42', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'c310b51e-83fa-4e5d-817a-850db23826a1' User entered 'No (N)'	System	30 Aug 2020 17:01:48
	System	30 Aug 2020 17:01:48

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-30T12:01:45', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'c310b51e-83fa-4e5d-817a-850db23826a1' User entered '30 Aug 2020 12:01'	System	30 Aug 2020 17:01:48
	System	30 Aug 2020 17:01:48

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 6'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:59:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:08', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '19791bf6-9b61-4e11-b153-cfe50fbff926' User entered 'None (0)'	System	31 Aug 2020 17:14:34
	System	31 Aug 2020 17:14:34

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:59:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:09', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '19791bf6-9b61-4e11-b153-cfe50fbff926' User entered 'None (0)'	System	31 Aug 2020 17:14:34
	System	31 Aug 2020 17:14:34

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:59:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:10', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '19791bf6-9b61-4e11-b153-cfe50fbff926' User entered 'None (0)'	System	31 Aug 2020 17:14:34
	System	31 Aug 2020 17:14:34

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:59:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:12', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '19791bf6-9b61-4e11-b153-cfe50fbff926' User entered 'None (0)'	System	31 Aug 2020 17:14:34
	System	31 Aug 2020 17:14:34

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:13', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '19791bf6-9b61-4e11-b153-cfe50fbff926' User entered 'None (0)'	System	31 Aug 2020 17:14:34
	System	31 Aug 2020 17:14:34

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:14', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '19791bf6-9b61-4e11-b153-cfe50fbff926' User entered 'None (0)'	System	31 Aug 2020 17:14:34
	System	31 Aug 2020 17:14:34

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:15', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '19791bf6-9b61-4e11-b153-cfe50fbff926' User entered 'No (N)'	System	31 Aug 2020 17:14:34
	System	31 Aug 2020 17:14:34

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-08-31T12:02:20', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '19791bf6-9b61-4e11-b153-cfe50fbff926' User entered '31 Aug 2020 12:02'	System	31 Aug 2020 17:14:34
	System	31 Aug 2020 17:14:34

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 21:40:25

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 7'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:59:21

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:16:07', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '63740731-4183-4c5a-b180-3ffd5a4e69f8'	System	01 Sep 2020 23:16:20
User entered 'No interference with activity (1)'	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:59:21

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:16:08', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '63740731-4183-4c5a-b180-3ffd5a4e69f8' User entered 'None (0)'	System	01 Sep 2020 23:16:20
	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:59:21

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:16:09', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '63740731-4183-4c5a-b180-3ffd5a4e69f8' User entered 'None (0)'	System	01 Sep 2020 23:16:20
	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:59:21

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:16:10', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '63740731-4183-4c5a-b180-3ffd5a4e69f8' User entered 'None (0)'	System	01 Sep 2020 23:16:20
	System	01 Sep 2020 23:16:20

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:16:11', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '63740731-4183-4c5a-b180-3ffd5a4e69f8' User entered 'None (0)'	System	01 Sep 2020 23:16:20
	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:59:21

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:16:13', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '63740731-4183-4c5a-b180-3ffd5a4e69f8' User entered 'None (0)'	System	01 Sep 2020 23:16:20
	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:16:15', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '63740731-4183-4c5a-b180-3ffd5a4e69f8' User entered 'No (N)'	System	01 Sep 2020 23:16:20
	System	01 Sep 2020 23:16:20

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-01T19:16:16', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '63740731-4183-4c5a-b180-3ffd5a4e69f8' User entered '01 Sep 2020 19:16'	System	01 Sep 2020 23:16:20
	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 21:40:25

**US3672333**

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

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

**Generated On: 11 Aug 2021 22:59:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	01 Sep 2020 23:16:20
User entered 'Day 8'	System	01 Sep 2020 23:16:20

**US3672333**

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

**Form: Headache\_Day(8)**

**Generated On: 11 Aug 2021 22:59:21**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-03T08:40:30', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '93393911-746c-4f7d-ab62-e3d766ad04e9' User entered 'None (0)'	System	03 Sep 2020 12:40:40
	System	03 Sep 2020 12:40:40

**US3672333**

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

**Form: Headache\_Day(8)**

**Generated On: 11 Aug 2021 22:59:21**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-03T08:40:35', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '93393911-746c-4f7d-ab62-e3d766ad04e9' User entered '03 Sep 2020 08:40'	System	03 Sep 2020 12:40:40
	System	03 Sep 2020 12:40:40

**US3672333**

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

**Form: Headache\_Day(8)**

**Generated On: 11 Aug 2021 22:59:21**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 23:16:20

**US3672333**

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

**Form: Headache\_Day(8)**

**Generated On: 11 Aug 2021 22:59:21**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	01 Sep 2020 23:16:20
User entered 'Day 8'	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-03T08:40:39', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '785461a1-2cb3-4c9d-b9a7-834f191a63a3' User entered 'No (N)'	System	03 Sep 2020 12:40:42
	System	03 Sep 2020 12:40:42

**US3672333**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:59:21**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-09-03T08:40:41', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '785461a1-2cb3-4c9d-b9a7-834f191a63a3' User entered '03 Sep 2020 08:40'	System	03 Sep 2020 12:40:42
	System	03 Sep 2020 12:40:42

US3672333

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 23:16:20

US3672333

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 23:16:20

**US3672333**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 13:37:12

US3672333

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '02 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 13:37:12

US3672333

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Sep 2020 13:37:12

**US3672333**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 13:37:12

US3672333

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 13:37:18

**US3672333**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'I'	System	03 Sep 2020 13:37:18

**US3672333**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	14 Sep 2020 17:38:19

US3672333

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '9 Sep 2020'	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:38:19

US3672333

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:38:19

US3672333

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:38:19

US3672333

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	Patty Howenstine (b) (4)	14 Sep 2020 17:38:23

US3672333

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered '1'	System	14 Sep 2020 17:38:23

US3672333

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
Query 'Per CDM: Visit 2 Day 29 has not been completed in the database; but GCL has a record of Visit 2 Day 29 Immunogenicity Sample dated 23SEP2020. Please review and reconcile and, if appropriate, complete the Immunogenicity Assessment.' canceled (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:17:02
User opened query 'Per CDM: Visit 2 Day 29 has not been completed in the database; but GCL has a record of Visit 2 Day 29 Immunogenicity Sample dated 23SEP2020. Please review and reconcile and, if appropriate, complete the Immunogenicity Assessment.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 09:57:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 15:46:52

US3672333

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:46:52

US3672333

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Sep 2020 15:46:52

US3672333

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 15:46:52

US3672333

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User closed query 'Per CDM: Visit 2 Day 29 has not been completed in the database; but Visit 2 Day 29 Immunogenicity Sample is expected at GCL. Please review and reconcile and, if appropriate, complete the Immunogenicity Assessment at Visit 2 Day 29.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 10:13:45
Query 'Per CDM: Visit 2 Day 29 has not been completed in the database; but Visit 2 Day 29 Immunogenicity Sample is expected at GCL. Please review and reconcile and, if appropriate, complete the Immunogenicity Assessment at Visit 2 Day 29.' answered with 'Data has been entered.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 13:28:38
User opened query 'Per CDM: Visit 2 Day 29 has not been completed in the database; but Visit 2 Day 29 Immunogenicity Sample is expected at GCL. Please review and reconcile and, if appropriate, complete the Immunogenicity Assessment at Visit 2 Day 29.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:17:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 15:46:55

US3672333

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'I'	System	16 Sep 2020 15:46:55

US3672333

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 19:56:34

US3672333

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '23 Sep 2020'	(b) (4), (b) (6)	11 Oct 2020 19:56:34

US3672333

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Oct 2020 19:56:34

**US3672333**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'VISIT2'	System	11 Oct 2020 19:56:34

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '23 Sep 2020'	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '15:15'	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered '23 Sep 2020 15:15'	System	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '98.4' F	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '78'	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'bpm'	System	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '17'	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'breaths/min'	System	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '137'	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'mmHg'	System	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '89'	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'mmHg'	System	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered empty.	System	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered empty.	System	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered empty.	System	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered empty.	System	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered empty.	System	11 Oct 2020 19:59:16

US3672333

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Oct 2020 20:04:11

US3672333

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Oct 2020 20:04:11

US3672333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:21

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 20:11:58

US3672333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:21

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '23 Sep 2020'	(b) (4), (b) (6)	11 Oct 2020 20:11:58

**US3672333**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Urine (URINE)'	(b) (4), (b) (6)	11 Oct 2020 20:11:58

**US3672333**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	11 Oct 2020 20:11:58

US3672333

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:21

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'No (N)'	(b) (4), (b) (6)	11 Oct 2020 20:11:58

**US3672333**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 20:11:58

**US3672333**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 20:11:58

**US3672333**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered empty.	System	11 Oct 2020 20:11:58

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'No (N)'	(b) (4), (b) (6)	11 Oct 2020 20:13:19

**US3672333**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:59:21**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Other (OTHER)'	(b) (4), (b) (6)	11 Oct 2020 20:13:19

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

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)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'No swab result found from Day 1'	(b) (4) (b) (4), (b) (6)	11 Oct 2020 20:13:19

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered empty.	System	11 Oct 2020 20:13:19

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 20:13:19

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 20:13:19

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered empty.	System	11 Oct 2020 20:13:19

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Oct 2020 20:13:19

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered empty.	System	11 Oct 2020 20:13:19

US3672333

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered empty.	System	11 Oct 2020 20:13:19

US3672333

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 20:12:51

US3672333

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '23 Sep 2020'	(b) (4), (b) (6)	11 Oct 2020 20:12:51

US3672333

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '15:30'	(b) (4), (b) (6)	11 Oct 2020 20:12:51

US3672333

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered '23 Sep 2020 15:30'	System	11 Oct 2020 20:12:51

US3672333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:59:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Oct 2020 20:13:38

**US3672333**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 22:59:21**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Oct 2020 20:13:38

US3672333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Oct 2020 20:13:38

**US3672333**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '15:30'	(b) (4), (b) (6)	11 Oct 2020 20:13:38

US3672333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered '23 Sep 2020 15:30'	System	11 Oct 2020 20:13:38

**US3672333**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 22:59:21**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Oct 2020 20:13:38

US3672333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Oct 2020 20:13:38

US3672333

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:59:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Oct 2020 20:13:38

**US3672333**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered empty.	System	11 Oct 2020 20:13:38

US3672333

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 20:13:41

**US3672333**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered '1'	System	11 Oct 2020 20:13:41

**US3672333**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'No (N)'	(b) (4), (b) (6)	11 Oct 2020 20:13:51

US3672333

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 20:13:51

US3672333

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 20:13:51

US3672333

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Oct 2020 20:13:51

US3672333

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Oct 2020 20:13:55

US3672333

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'I'	System	11 Oct 2020 20:13:55

**US3672333**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 20:14:02

**US3672333**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '11 Oct 2020'	(b) (4), (b) (6)	11 Oct 2020 20:14:02

US3672333

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Oct 2020 20:14:02

US3672333

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Oct 2020 20:14:02

US3672333

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 20:14:05

US3672333

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'I'	System	11 Oct 2020 20:14:05

**US3672333**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 15:04:28

US3672333

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 15:04:28

US3672333

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Oct 2020 15:04:28

US3672333

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:04:28

US3672333

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 15:04:42

**US3672333**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered '1'	System	14 Oct 2020 15:04:42

**US3672333**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 20:35:58

**US3672333**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:35:58

US3672333

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:35:58

**US3672333**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'VISIT3'	System	21 Oct 2020 20:35:58

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:36:44

**US3672333**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '16:16'	(b) (4), (b) (6)	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered '21 Oct 2020 16:16'	System	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '98.2' F	(b) (4), (b) (6)	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:36:44

**US3672333**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '80'	(b) (4), (b) (6)	21 Oct 2020 20:36:44

**US3672333**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'bpm'	System	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '16'	(b) (4), (b) (6)	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'breaths/min'	System	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '109'	(b) (4), (b) (6)	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'mmHg'	System	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '68'	(b) (4), (b) (6)	21 Oct 2020 20:36:44

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'mmHg'	System	21 Oct 2020 20:36:44

**US3672333**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18

US3672333

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18

US3672333

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:36:51

US3672333

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 20:36:51

US3672333

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 20:42:22

US3672333

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '21 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 20:42:22

US3672333

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered '16:32'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:42:22

US3672333

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered '21 Oct 2020 16:32'	System	21 Oct 2020 20:42:22

US3672333

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:01:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:42:28

**US3672333**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered '1'	System	21 Oct 2020 20:42:28

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 64'	System	26 Aug 2020 21:40:25

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-10-26T00:01:30', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a8962d61-2e8a-4bf5-8806-6570e1010118' User entered 'No (N)'	System	26 Oct 2020 04:01:55
	System	26 Oct 2020 04:01:55

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-10-26T00:01:33', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a8962d61-2e8a-4bf5-8806-6570e1010118'	System	26 Oct 2020 04:01:55
User entered 'No (N)'	System	26 Oct 2020 04:01:55

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-10-26T00:01:49', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a8962d61-2e8a-4bf5-8806-6570e1010118' User entered '26 Oct 2020 00:01:49'	System	26 Oct 2020 04:01:55
	System	26 Oct 2020 04:01:55

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered '26 Oct 2020 00:01'	System	26 Aug 2020 21:40:25

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered '30 Oct 2020 23:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 71'	System	26 Aug 2020 21:40:25

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-02T00:01:23', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'd0f65598-bef0-48b6-8651-c8c5c4b32818'	System	02 Nov 2020 05:01:33
User entered 'No (N)'	System	02 Nov 2020 05:01:33

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-02T00:01:27', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'd0f65598-bef0-48b6-8651-c8c5c4b32818'	System	02 Nov 2020 05:01:33
User entered 'No (N)'	System	02 Nov 2020 05:01:33

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-02T00:01:30', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'd0f65598-bef0-48b6-8651-c8c5c4b32818' User entered '02 Nov 2020 00:01:30'	System	02 Nov 2020 05:01:33
	System	02 Nov 2020 05:01:33

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered '02 Nov 2020 00:01'	System	26 Aug 2020 21:40:25

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered '06 Nov 2020 23:59'	System	26 Aug 2020 21:40:25

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered 'Day 78'	System	26 Aug 2020 21:40:25

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-11T12:00:52', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '248e6b34-a91d-4423-a6c0-abeb60e196e3' User entered 'No (N)'	System	11 Nov 2020 17:01:32
	System	11 Nov 2020 17:01:32

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-11T12:00:55', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '248e6b34-a91d-4423-a6c0-abeb60e196e3' User entered 'No (N)'	System	11 Nov 2020 17:01:32
	System	11 Nov 2020 17:01:32

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-11T12:01:06', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '248e6b34-a91d-4423-a6c0-abeb60e196e3' User entered '11 Nov 2020 12:01:06'	System	11 Nov 2020 17:01:32
	System	11 Nov 2020 17:01:32

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered '09 Nov 2020 00:01'	System	26 Aug 2020 21:40:25

US3672333

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:28:28
Data entry locked.	System	26 Aug 2020 21:40:25
User entered '13 Nov 2020 23:59'	System	26 Aug 2020 21:40:25

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[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 (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-23T00:01:48', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '7656025c-3768-40f8-9e7e-dd877bafba01' User entered 'No (N)'	System	23 Nov 2020 05:01:56

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Have you been exposed to someone with 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 (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-23T00:01:49', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '7656025c-3768-40f8-9e7e-dd877bafba01' User entered 'No (N)'	System	23 Nov 2020 05:01:56

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-23T00:01:51', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '7656025c-3768-40f8-9e7e-dd877bafba01' User entered '23 Nov 2020 00:01:51'	System	23 Nov 2020 05:01:56
	System	23 Nov 2020 05:01:56

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[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 (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-27T00:01:12', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'e1b0f0be-73a5-497b-b573-4350532f7a81' User entered 'No (N)'	System	27 Nov 2020 05:01:21

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Have you been exposed to someone with 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 (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-27T00:01:15', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'e1b0f0be-73a5-497b-b573-4350532f7a81' User entered 'No (N)'	System	27 Nov 2020 05:01:21

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-11-27T00:01:17', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'e1b0f0be-73a5-497b-b573-4350532f7a81' User entered '27 Nov 2020 00:01:17'	System	27 Nov 2020 05:01:21
	System	27 Nov 2020 05:01:21

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[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 (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-12-04T17:32:39', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '30473eb1-a9c2-4db1-b6ef-703b0031eaa9' User entered 'No (N)'	System	04 Dec 2020 23:32:44
	System	04 Dec 2020 23:32:44

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Have you been exposed to someone with 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 (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-12-04T17:32:41', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '30473eb1-a9c2-4db1-b6ef-703b0031eaa9' User entered 'No (N)'	System	04 Dec 2020 23:32:44

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-12-04T17:32:42', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '30473eb1-a9c2-4db1-b6ef-703b0031eaa9' User entered '04 Dec 2020 17:32:42'	System	04 Dec 2020 23:32:44
	System	04 Dec 2020 23:32:44

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[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 (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-12-11T00:03:27', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'b622babf-f567-49ca-9430-4a8295ad4df3'	System	11 Dec 2020 05:04:36
User entered 'No (N)'	System	11 Dec 2020 05:04:36

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Have you been exposed to someone with 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 (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-12-11T00:03:28', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'b622babf-f567-49ca-9430-4a8295ad4df3'	System	11 Dec 2020 05:04:36
User entered 'Yes (Y)'	System	11 Dec 2020 05:04:36

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Please 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 (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-12-11T00:03:38', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'b622babf-f567-49ca-9430-4a8295ad4df3'	System	11 Dec 2020 05:04:36
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Dec 2020 05:04:36

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-12-11T00:04:28', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'b622babf-f567-49ca-9430-4a8295ad4df3' User entered '11 Dec 2020 00:04:28'	System	11 Dec 2020 05:04:36
	System	11 Dec 2020 05:04:36

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[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 (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-12-18T00:01:31', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '7fc741ce-dba0-436f-b191-cf70e6f734fc' User entered 'No (N)'	System	18 Dec 2020 05:01:59
	System	18 Dec 2020 05:01:59

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Have you been exposed to someone with 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 (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-12-18T00:01:38', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '7fc741ce-dba0-436f-b191-cf70e6f734fc' User entered 'No (N)'	System	18 Dec 2020 05:01:59

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-12-18T00:01:40', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '7fc741ce-dba0-436f-b191-cf70e6f734fc' User entered '18 Dec 2020 00:01:40'	System	18 Dec 2020 05:01:59
	System	18 Dec 2020 05:01:59

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 18:34:00

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[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 (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-12-25T21:35:38', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '6372284d-464c-4e13-9075-7c4459dfe693'	System	26 Dec 2020 02:35:58
User entered 'No (N)'	System	26 Dec 2020 02:35:58

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

Have you been exposed to someone with 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 (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-12-25T21:35:51', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '6372284d-464c-4e13-9075-7c4459dfe693'	System	26 Dec 2020 02:35:58
User entered 'No (N)'	System	26 Dec 2020 02:35:58

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E7A1034E-F273-46E4-AEF6-55A49A2B16FC)', Time: '2020-12-25T21:35:55', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '6372284d-464c-4e13-9075-7c4459dfe693' User entered '25 Dec 2020 21:35:55'	System	26 Dec 2020 02:35:58
	System	26 Dec 2020 02:35:58

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:34:00

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-02-12T13:48:51', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'b70d7347-1cb8-4e51-a1d0-4e2e5bfb2295'	System	12 Feb 2021 18:49:20
User entered 'No (N)'	System	12 Feb 2021 18:49:20

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Have you been exposed to someone with 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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-02-12T13:48:54', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'b70d7347-1cb8-4e51-a1d0-4e2e5bfb2295'	System	12 Feb 2021 18:49:20
User entered 'No (N)'	System	12 Feb 2021 18:49:20

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-02-12T13:48:57', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'b70d7347-1cb8-4e51-a1d0-4e2e5bfb2295' User entered '12 Feb 2021 13:48:57'	System	12 Feb 2021 18:49:20

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-02-19T20:58:17', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'f0586473-1b94-4749-8877-7537a0bc17b7' User entered 'No (N)'	System	20 Feb 2021 01:58:25
	System	20 Feb 2021 01:58:25

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Have you been exposed to someone with 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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-02-19T20:58:20', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'f0586473-1b94-4749-8877-7537a0bc17b7'	System	20 Feb 2021 01:58:25
User entered 'No (N)'	System	20 Feb 2021 01:58:25

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-02-19T20:58:23', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'f0586473-1b94-4749-8877-7537a0bc17b7'	System	20 Feb 2021 01:58:25
User entered '19 Feb 2021 20:58:23'	System	20 Feb 2021 01:58:25

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-02-26T00:02:27-05:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '9e0df4f0-55b4-40ce-97f3-d2589466a20e' User entered 'No (N)'	System	26 Feb 2021 09:21:11
	System	26 Feb 2021 09:21:11

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

Have you been exposed to someone with 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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-02-26T00:02:30-05:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '9e0df4f0-55b4-40ce-97f3-d2589466a20e' User entered 'No (N)'	System	26 Feb 2021 09:21:11
	System	26 Feb 2021 09:21:11

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-02-26T00:02:34-05:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '9e0df4f0-55b4-40ce-97f3-d2589466a20e' User entered '26 Feb 2021 05:02:34'	System	26 Feb 2021 09:21:11
	System	26 Feb 2021 09:21:11

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-03-06T00:57:48-05:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'dbdb4ef8-0aeb-4f3e-ba38-3c15f611d1fa'	System	06 Mar 2021 06:08:19
User entered 'No (N)'	System	06 Mar 2021 06:08:19

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Have you been exposed to someone with 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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-03-06T00:57:52-05:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'dbdb4ef8-0aeb-4f3e-ba38-3c15f611d1fa'	System	06 Mar 2021 06:08:19
User entered 'No (N)'	System	06 Mar 2021 06:08:19

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-03-06T00:57:56-05:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'dbdb4ef8-0aeb-4f3e-ba38-3c15f611d1fa' User entered '06 Mar 2021 05:57:56'	System	06 Mar 2021 06:08:19
	System	06 Mar 2021 06:08:19

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-03-12T01:27:04-05:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'fd175c0e-7cfd-422c-a981-05af715caab5'	System	12 Mar 2021 06:27:16
User entered 'No (N)'	System	12 Mar 2021 06:27:16

US3672333

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:59:21

Have you been exposed to someone with 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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-03-12T01:27:11-05:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'fd175c0e-7cfd-422c-a981-05af715caab5'	System	12 Mar 2021 06:27:16
User entered 'No (N)'	System	12 Mar 2021 06:27:16

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-03-12T01:27:13-05:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'fd175c0e-7cfd-422c-a981-05af715caab5' User entered '12 Mar 2021 01:27:13'	System	12 Mar 2021 06:27:16
	System	12 Mar 2021 06:27:16

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-03-19T10:04:00-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '77bb4c6c-5d40-442f-8eec-dbb05775f77c' User entered 'No (N)'	System	26 Mar 2021 22:19:54
	System	26 Mar 2021 22:19:54

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Have you been exposed to someone with 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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-03-19T10:04:07-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '77bb4c6c-5d40-442f-8eec-dbb05775f77c' User entered 'Yes (Y)'	System	26 Mar 2021 22:19:54
	System	26 Mar 2021 22:19:54

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Please 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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-03-19T10:04:12-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '77bb4c6c-5d40-442f-8eec-dbb05775f77c'	System	26 Mar 2021 22:19:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Mar 2021 22:19:54

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-03-19T10:04:15-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '77bb4c6c-5d40-442f-8eec-dbb05775f77c' User entered '19 Mar 2021 10:04:15'	System	26 Mar 2021 22:19:54
	System	26 Mar 2021 22:19:54

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-03-26T18:19:46-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '37be4531-9935-4976-887c-460b61d7fe5e'	System	26 Mar 2021 22:20:08
User entered 'No (N)'	System	26 Mar 2021 22:20:08

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Have you been exposed to someone with 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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-03-26T18:19:57-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '37be4531-9935-4976-887c-460b61d7fe5e'	System	26 Mar 2021 22:20:08
User entered 'No (N)'	System	26 Mar 2021 22:20:08

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-03-26T18:19:59-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '37be4531-9935-4976-887c-460b61d7fe5e' User entered '26 Mar 2021 18:19:59'	System	26 Mar 2021 22:20:08
	System	26 Mar 2021 22:20:08

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-04-02T00:02:16-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'd93f9cf4-3efc-4b59-9990-2b7eec77cbe0' User entered 'No (N)'	System	02 Apr 2021 04:03:59
	System	02 Apr 2021 04:03:59

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Have you been exposed to someone with 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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-04-02T00:02:20-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'd93f9cf4-3efc-4b59-9990-2b7eec77cbe0' User entered 'No (N)'	System	02 Apr 2021 04:03:59

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-04-02T00:02:22-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'd93f9cf4-3efc-4b59-9990-2b7eec77cbe0' User entered '02 Apr 2021 00:02:22'	System	02 Apr 2021 04:03:59
	System	02 Apr 2021 04:03:59

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-04-10T14:54:44-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'fbd7432a-412e-4ab5-ad8b-6ee29582f5f2'	System	10 Apr 2021 18:54:50
User entered 'No (N)'	System	10 Apr 2021 18:54:50

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Have you been exposed to someone with 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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-04-10T14:54:46-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'fbd7432a-412e-4ab5-ad8b-6ee29582f5f2'	System	10 Apr 2021 18:54:50
User entered 'No (N)'	System	10 Apr 2021 18:54:50

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-04-10T14:54:48-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'fbd7432a-412e-4ab5-ad8b-6ee29582f5f2' User entered '10 Apr 2021 14:54:48'	System	10 Apr 2021 18:54:50
	System	10 Apr 2021 18:54:50

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-04-16T10:10:53-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '273e71ff-f57b-4ac4-b5c4-c93ddf570dfc' User entered 'No (N)'	System	16 Apr 2021 14:11:00
	System	16 Apr 2021 14:11:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Have you been exposed to someone with 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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-04-16T10:10:54-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '273e71ff-f57b-4ac4-b5c4-c93ddf570dfc' User entered 'No (N)'	System	16 Apr 2021 14:11:00
	System	16 Apr 2021 14:11:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-04-16T10:10:57-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '273e71ff-f57b-4ac4-b5c4-c93ddf570dfc' User entered '16 Apr 2021 10:10:57'	System	16 Apr 2021 14:11:00
	System	16 Apr 2021 14:11:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-04-23T16:17:23-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'b1bdf757-8efa-4dd3-8248-1a92acc04fa4'	System	23 Apr 2021 20:17:30
User entered 'No (N)'	System	23 Apr 2021 20:17:30

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Have you been exposed to someone with 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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-04-23T16:17:25-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'b1bdf757-8efa-4dd3-8248-1a92acc04fa4'	System	23 Apr 2021 20:17:30
User entered 'No (N)'	System	23 Apr 2021 20:17:30

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-04-23T16:17:27-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'b1bdf757-8efa-4dd3-8248-1a92acc04fa4'	System	23 Apr 2021 20:17:30
User entered '23 Apr 2021 16:17:27'	System	23 Apr 2021 20:17:30

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-04-30T05:22:48-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '6050608b-af0c-4b2a-890c-ef490172fe4e' User entered 'No (N)'	System	30 Apr 2021 09:22:57

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

Have you been exposed to someone with 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 (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-04-30T05:22:50-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '6050608b-af0c-4b2a-890c-ef490172fe4e' User entered 'No (N)'	System	30 Apr 2021 09:22:57

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-04-30T05:22:52-04:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: '6050608b-af0c-4b2a-890c-ef490172fe4e' User entered '30 Apr 2021 05:22:52'	System	30 Apr 2021 09:22:57
	System	30 Apr 2021 09:22:57

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:34:00

**US3672333**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 18:34:00

**US3672333**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:59:21**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:34:00
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 18:34:00

US3672333

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:59:21**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:28:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-03-06T00:58:02-05:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a1bce1b5-92ea-4856-8ef7-e4ff0fa8c616'	System	09 Mar 2021 00:23:16
User entered 'No (N)'	System	09 Mar 2021 00:23:16

**US3672333**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:28:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F20AC69E-E49D-4AD1-A5EA-31B5383CFECA)', Time: '2021-03-06T00:58:13-05:00', User OID: 'PatientReportedOutcome (US3672333)', ODM File OID: 'a1bce1b5-92ea-4856-8ef7-e4ff0fa8c616' User entered '06 Mar 2021 05:58:13'	System	09 Mar 2021 00:23:16
	System	09 Mar 2021 00:23:16

**US3672333**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:31:28

US3672333

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:31:28

US3672333

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:31:28

**US3672333**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:31:28

US3672333

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:31:32

**US3672333**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:58:18
User entered 'I'	System	19 Nov 2020 20:31:32

**US3672333**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:25:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Dec 2020 16:46:14

**US3672333**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:25:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '22 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:46:14

US3672333

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:25:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:46:14

**US3672333**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:25:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:46:14

US3672333

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:25:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:46:25

**US3672333**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:25:09
User entered 'I'	System	23 Dec 2020 16:46:25

**US3672333**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:25:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Jan 2021 20:35:26

US3672333

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:25:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:35:26

US3672333

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:25:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Jan 2021 20:35:26

**US3672333**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:25:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:35:26

US3672333

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:25:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:35:31

**US3672333**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:25:09
User entered '1'	System	21 Jan 2021 20:35:31

US3672333

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:08:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 12-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:07:53
Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 12-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'added' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 12:24:17
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 12-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 05:16:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 17:38:08

**US3672333**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:08:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:38:08

US3672333

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:08:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:38:08

US3672333

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:08:45
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 17:38:08

US3672333

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:08:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 17:38:13

**US3672333**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:08:45
User entered 'I'	System	17 Feb 2021 17:38:13

US3672333

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 21:04:41

US3672333

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
	(b) (4)	
User entered '12 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:04:41

US3672333

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:21

[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 13:18:40
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Mar 2021 21:04:41

**US3672333**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User entered 'VISIT4'	System	12 Mar 2021 21:04:41

US3672333

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 20:26:55

US3672333

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:26:55

**US3672333**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:26:55

US3672333

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User entered empty.	System	31 Mar 2021 20:26:55

US3672333

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:26:55

US3672333

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:26:55

US3672333

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:26:55

US3672333

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:26:55

US3672333

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User entered empty.	System	31 Mar 2021 20:26:55

US3672333

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:26:55

US3672333

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User entered empty.	System	31 Mar 2021 20:26:55

US3672333

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:26:55

US3672333

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User entered empty.	System	31 Mar 2021 20:26:55

US3672333

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:26:55

US3672333

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User entered empty.	System	31 Mar 2021 20:26:55

US3672333

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40

US3672333

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40

US3672333

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 16:15:37
User entered 'No (N)'	(b) (4), (b) (6)	12 Mar 2021 21:04:17

US3672333

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
	(b) (4)	
User entered '12 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 16:15:37
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:04:17

US3672333

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 21:04:09

US3672333

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
	(b) (4)	
User entered '12 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 21:04:09

US3672333

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
	(b) (4)	
User entered '14:14'	(b) (4), (b) (6)	12 Mar 2021 21:04:09

US3672333

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User entered '12 Mar 2021 14:14'	System	12 Mar 2021 21:04:09

US3672333

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 21:04:13

US3672333

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:18:40
User entered 'I'	System	12 Mar 2021 21:04:13

US3672333

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:04:36

US3672333

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:04:36

US3672333

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:04:36

US3672333

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:04:36

US3672333

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:04:41

**US3672333**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 22:04:41

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:21

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:56
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '24 Mar 2021'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:00:27

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:21

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:56
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '13:45'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:00:27

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:21

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:56
User entered '24 Mar 2021 13:45'	System	25 Mar 2021 20:00:27

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:21

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:56
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:00:27

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:21

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:56
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:00:27

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Day 1 (Day 1)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '18 Mar 2021'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '0'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User entered empty.	System	25 Mar 2021 20:01:30

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:01:30

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Day 2 (Day 2)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '19 Mar 2021'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '0'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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Form: Symptom Log (2)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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**Folder: Covid-19 Assessment 24 Mar 2021**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:59:21**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User entered empty.	System	25 Mar 2021 20:02:21

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (2)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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Form: Symptom Log (2)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (2)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (2)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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Form: Symptom Log (2)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:02:21

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Day 3 (Day 3)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '20 Mar 2021'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '0'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

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Generated On: 11 Aug 2021 22:59:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User entered empty.	System	25 Mar 2021 20:03:42

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

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Form: Symptom Log (3)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

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Form: Symptom Log (3)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:03:42

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Day 4 (Day 4)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:05:18

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '21 Mar 2021'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:05:18

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '0'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:05:18

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:05:18

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User entered empty.	System	25 Mar 2021 20:05:18

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:05:18

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:05:18

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:05:18

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:05:18

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:05:18

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:05:18

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:05:18

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:05:18

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:05:18

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:05:18

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:05:18

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Form: Symptom Log (4)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:05:18

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Form: Symptom Log (4)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:05:18

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Form: Symptom Log (4)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Patty Howenstine (b) (4)	25 Mar 2021 20:06:25
User entered empty.	(b) (4)	
	Patty Howenstine (b) (4)	25 Mar 2021 20:05:18
	(b) (4)	

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Form: Symptom Log (4)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:05:18

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:05:18

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (4)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:05:18

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Day 5 (Day 5)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '22 Mar 2021'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '0'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User entered empty.	System	25 Mar 2021 20:06:25

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (5)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (5)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

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Form: Symptom Log (5)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:59:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:06:25

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Day 6 (Day 6)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '23 Mar 2021'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '0'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User entered empty.	System	25 Mar 2021 20:07:31

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Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

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Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (6)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

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Form: Symptom Log (6)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

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Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:59:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (6)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:07:31

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Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Day 7 (Day 7)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '24 Mar 2021'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '0'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

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Form: Symptom Log (7)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '99'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User entered '%'	System	25 Mar 2021 20:08:50

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '99.1' F	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

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Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

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Form: Symptom Log (7)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (7)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

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Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

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Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:59:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:08:50

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Day 8 (Day 8)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '25 Mar 2021'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '0'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '97'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User entered '%'	System	25 Mar 2021 20:11:14

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '96.8' F	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

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Form: Symptom Log (8)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

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Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

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Form: Symptom Log (8)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Mild (Mild)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

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Form: Symptom Log (8)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (8)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:59:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:14

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (9)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:02

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:02

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '0'	(b) (4), (b) (6)	26 Mar 2021 18:42:02

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '99'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:02

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User entered '%'	System	26 Mar 2021 18:42:02

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:02

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:02

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:02

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:02

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:02

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:02

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:02

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Form: Symptom Log (9)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:02

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Generated On: 11 Aug 2021 22:59:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:02

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:02

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:02

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:02

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:02

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:02

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Form: Symptom Log (9)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:02

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Generated On: 11 Aug 2021 22:59:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:02

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:42:02

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:19:48

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:59:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '27 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:19:48

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 20:19:48

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '99'	(b) (4), (b) (6)	29 Mar 2021 20:19:48

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User entered '%'	System	29 Mar 2021 20:19:48

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (10)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:19:48

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:19:48

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:19:48

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:19:48

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:19:48

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:19:48

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:19:48

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:19:48

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:19:48

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Form: Symptom Log (10)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:19:48

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4), (b) (6)	29 Mar 2021 20:19:48

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:19:48

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Form: Symptom Log (10)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:19:48

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:19:48

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:19:48

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Form: Symptom Log (10)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:19:48

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:19:48

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Generated On: 11 Aug 2021 22:59:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:23

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Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '28 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:23

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Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:23

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Form: Symptom Log (11)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '99'	(b) (4), (b) (6)	29 Mar 2021 20:20:23

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User entered '%'	System	29 Mar 2021 20:20:23

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Form: Symptom Log (11)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '99.4' F	(b) (4), (b) (6)	29 Mar 2021 20:20:23

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Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:23

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Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:23

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Form: Symptom Log (11)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:23

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:23

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (11)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:23

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:23

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:23

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:59:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:23

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (11)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4), (b) (6)	29 Mar 2021 20:20:23

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:23

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Form: Symptom Log (11)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:23

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:23

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:23

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:23

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:23

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:23

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:56

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:56

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 20:20:56

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '98'	(b) (4), (b) (6)	29 Mar 2021 20:20:56

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Form: Symptom Log (12)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User entered '%'	System	29 Mar 2021 20:20:56

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:56

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Generated On: 11 Aug 2021 22:59:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:56

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:56

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4), (b) (6)	29 Mar 2021 20:20:56

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:56

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:56

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:56

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:56

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:56

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:56

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4), (b) (6)	29 Mar 2021 20:20:56

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:56

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:56

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:56

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:56

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:56

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:20:56

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Day 13 (Day 13)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:55:00

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Form: Symptom Log (13)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:55:00

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 22:55:00

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '98'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:55:00

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User entered '%'	System	30 Mar 2021 22:55:00

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '97.9' F	(b) (4), (b) (6)	30 Mar 2021 22:55:00

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:55:00

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:55:00

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:55:00

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:55:00

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:55:00

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:55:00

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:55:00

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:55:00

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:55:00

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:55:00

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:55:00

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Severe (Severe)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:55:00

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:55:00

US3672333

Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:55:00

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:55:00

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Folder: Covid-19 Assessment 24 Mar 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:59:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:55:00

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Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:21

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:15
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:18:50

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Folder: Covid-19 Assessment 24 Mar 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:21

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:15
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:18:50

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Folder: Covid-19 Assessment 24 Mar 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:21

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:15
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Apr 2021 16:16:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Apr 2021 16:16:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 16:16:57
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 20:18:50
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:18:50

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Folder: Covid-19 Assessment 24 Mar 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:21

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:15
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:18:50

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Folder: Covid-19 Assessment 24 Mar 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:21

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:15
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	29 Mar 2021 20:18:50

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Folder: Covid-19 Assessment 24 Mar 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:21

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:15
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:18:50

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Folder: Covid-19 Assessment 24 Mar 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:21

[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)	03 May 2021 15:22:15
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:18:50

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Folder: Covid-19 Assessment 24 Mar 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:21

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:15
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:18:50

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Folder: Covid-19 Assessment 24 Mar 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:21

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:15
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:18:50

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Folder: Covid-19 Assessment 24 Mar 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:21

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:22:15
User entered '0'	System	13 Apr 2021 16:16:57

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

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[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:07:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
Query 'Per GCL Lab Reconciliation: Saliva: Re-query: Thank you for the response, however please confirm the correct date for Day 3 saliva sample collected. Thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:34:54
User opened query 'Per GCL Lab Reconciliation: Saliva: Re-query: Thank you for the response, however please confirm the correct date for Day 3 saliva sample collected. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:31:23
User closed query 'Per GCL Lab Reconciliation: Saliva: Re-query: Response noted, however please confirm the sample collection date as Sample dated 02OCT2020 is reported under Illness Visits in PPD Central lab, thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:31:23
Query 'Per GCL Lab Reconciliation: Saliva: Re-query: Response noted, however please confirm the sample collection date as Sample dated 02OCT2020 is reported under Illness Visits in PPD Central lab, thank you.' answered with 'Date must be reconciled by PPD central lab, date is unable to be changed by site.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 20:24:15
User opened query 'Per GCL Lab Reconciliation: Saliva: Re-query: Response noted, however please confirm the sample collection date as Sample dated 02OCT2020 is reported under Illness Visits in PPD Central lab, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 05:47:43
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Saliva Collection form of the illness visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 05:47:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:21

[Date of Contact](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Saliva Collection form of the illness visit. Else clarify, thank you.' answered with 'subject performed a saliva swab at an outside facility.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 14:21:42
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Saliva Collection form of the illness visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:40:44
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 14:37:36

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:21

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:07:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '10:55'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:37:36

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:21

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:07:42
User entered '30 Sep 2020 10:55'	System	13 Oct 2020 14:37:36

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:59:21

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:07:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4), (b) (6)	13 Oct 2020 14:37:36

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

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[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:07:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:37:36

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

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[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Day 1 (Day 1)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:38:33

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '30 Sep 2020'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:38:33

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Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

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Form: Symptom Log (1)

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[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '100'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:38:33

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
User entered '%'	System	13 Oct 2020 14:38:33

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Form: Symptom Log (1)

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[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
	(b) (4)	
User entered '98.5' F	(b) (4), (b) (6)	13 Oct 2020 14:38:33

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Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:38:33

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Form: Symptom Log (1)

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[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:38:33

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Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

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Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:38:33

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:38:33

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:38:33

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:38:33

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Mild (Mild)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:38:33

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:38:33

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:38:33

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:38:33

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:38:33

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:59:21

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:38:33

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Day 2 (Day 2)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:39:26

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '1 Oct 2020'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:39:26

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '100'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:39:26

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
User entered '%'	System	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
	(b) (4)	
User entered '98.6' F	(b) (4), (b) (6)	13 Oct 2020 14:39:26

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:39:26

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:39:26

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:39:26

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:39:26

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:39:26

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:39:26

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:39:26

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
	(b) (4)	
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:39:26

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:39:26

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:39:26

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:59:21

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:39:26

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
	(b) (4)	
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Date](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '2 Oct 2020'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[O2 Saturation](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '100'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
User entered '%'	System	13 Oct 2020 14:40:25

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Temperature](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '98.9' F	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Chills](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Cough](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Fatigue](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Body Aches](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Headache](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
	(b) (4)	
User entered 'None (None)'	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Severe (Severe)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Form: Symptom Log (3)

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[Nausea](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Vomiting](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Diarrhea](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:59:21

[Sore Throat](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	03 May 2021 15:34:38
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 15:21:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 15:13:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'None (None)'	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:40:25

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:59:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:28
Data entry locked.	(b) (4), (b) (6)	03 May 2021 15:20:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	03 May 2021 15:13:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 May 2021 15:13:32

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:21

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User closed query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 30 SEP 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 05:29:38
Query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 30 SEP 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 19:22:50
User opened query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 30 SEP 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:19:00
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 14:40:55

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:21

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:40:55

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:21

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
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	13 Oct 2020 19:36:59
User entered 'No (N)' reason for change: Data Entry Error	Cynthia Strout (b) (4)	13 Oct 2020 19:36:59
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	13 Oct 2020 19:35:14
User entered 'No (N)'	Cynthia Strout (b) (4)	13 Oct 2020 19:35:14
	(b) (4)	
	(b) (4), (b) (6)	13 Oct 2020 14:40:55

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:21

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:40:55

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:21

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	13 Oct 2020 14:40:55

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:21

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:40:55

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:21

[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)	03 May 2021 15:21:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:40:55

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:21

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:40:55

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:21

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:40:55

US3672333

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:59:21

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:21:37
User entered '0'	System	13 Oct 2020 14:40:55

**US3672333**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

**US3672333**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:23:24

US3672333

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:59:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 30SEP2020 for Day 3 is recorded in EDC, however sample is reported with 02OCT2020 for Day 3 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 06:16:40
Query 'Per GCL Lab Recon: Saliva: Sample dated 30SEP2020 for Day 3 is recorded in EDC, however sample is reported with 02OCT2020 for Day 3 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' answered with 'fixed' (Site from DM).	Patty Howenstine (b) (4) (b) (4)	11 Feb 2021 20:05:48
User entered '02 Oct 2020' reason for change: Data Entry Error	Patty Howenstine (b) (4) (b) (4)	11 Feb 2021 20:05:41
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 30SEP2020 for Day 3 is recorded in EDC, however sample is reported with 02OCT2020 for Day 3 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 04:35:43
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30SEP2020 is recorded under Illness visit 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.' canceled (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 04:34:28
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30SEP2020 is recorded under Illness visit 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)	04 Dec 2020 11:07:48
User entered '30 Sep 2020'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

**US3672333**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

**US3672333**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:23:24

**US3672333**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:23:24

**US3672333**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:59:21**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

**US3672333**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:59:21**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:23:24

**US3672333**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:59:21**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:23:24

**US3672333**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:59:21**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

**US3672333**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:59:21**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:23:24

**US3672333**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:59:21**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:23:24

**US3672333**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:59:21**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

**US3672333**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:59:21**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:23:24

**US3672333**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:59:21**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:23:24

**US3672333**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:59:21**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

**US3672333**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:59:21**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:23:24

**US3672333**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:59:21**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:23:24

**US3672333**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:59:21**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	16 Nov 2020 22:23:24

**US3672333**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:59:21**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:23:24

**US3672333**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:59:21**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:58:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:23:24

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:03

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 22:22:40
User entered '20 Sep 2020'	(b) (4), (b) (6)	16 Nov 2020 22:21:03

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:03

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:37
User entered 'SICKD1'	System	16 Nov 2020 22:21:03

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	16 Nov 2020 22:22:54
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	16 Nov 2020 22:22:54
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 22:22:54
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Nov 2020 22:22:40
User entered '20 Sep 2020'	(b) (4), (b) (6)	16 Nov 2020 22:21:43

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '10:55'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:43

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:45
User entered '30 Sep 2020 10:55'	System	16 Nov 2020 22:22:54
User entered '20 Sep 2020 10:55'	System	16 Nov 2020 22:21:43

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '160.0' cm	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:43
DataPoint set to visible.	System	16 Nov 2020 22:21:03

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '78.7' kg	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:43
DataPoint set to visible.	System	16 Nov 2020 22:21:03

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '68'	(b) (4), (b) (6)	16 Nov 2020 22:21:43

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:45
User entered 'bpm'	System	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '20'	(b) (4), (b) (6)	16 Nov 2020 22:21:43

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:45
User entered 'breaths/min'	System	16 Nov 2020 22:21:43

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '102'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:43

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:45
User entered 'mmHg'	System	16 Nov 2020 22:21:43

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '73'	(b) (4), (b) (6)	16 Nov 2020 22:21:43

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:45
User entered 'mmHg'	System	16 Nov 2020 22:21:43

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 May 2021 08:57:45

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:45

US3672333

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:21:51

US3672333

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Nov 2020 22:22:40
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Nov 2020 22:22:33
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 22:22:33
User entered '20 Sep 2020'	(b) (4), (b) (6)	16 Nov 2020 22:21:51

US3672333

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:59:21

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 22:22:02

US3672333

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:59:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:57:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 22:22:09
User entered '20 Sep 2020'	(b) (4), (b) (6)	16 Nov 2020 22:22:02

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:35

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '24 Mar 2021'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:35

US3672333

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Clinic (Clinic)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:11:35

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	25 Mar 2021 20:11:35

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:12:36

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '24 Mar 2021'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:12:36
	(b) (4)	

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '13:50'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:12:36
	(b) (4)	

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '24 Mar 2021 13:50'	System	25 Mar 2021 20:12:36

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Height (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '161.5' cm	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:12:36
DataPoint set to visible.	(b) (4) System	25 Mar 2021 20:11:35

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '77.5' kg	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:12:36
DataPoint set to visible.	(b) (4) System	25 Mar 2021 20:11:35

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '99.1' F	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:12:36
	(b) (4)	

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Oral (Oral)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:12:36
	(b) (4)	

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:12:36

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '70'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:12:36
	(b) (4)	

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Mar 2021 20:12:36

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '15'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:12:36

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Mar 2021 20:12:36

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '121'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:12:36

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Mar 2021 20:12:36

US3672333

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '72'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:12:36
	(b) (4)	

**US3672333**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Mar 2021 20:12:36

US3672333

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:12:44

US3672333

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '24 Mar 2021'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:12:44
	(b) (4)	

US3672333

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 22:59:21**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:12:53

US3672333

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 22:59:21**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '24 Mar 2021'	(b) (4) Patty Howenstine (b) (4)	25 Mar 2021 20:12:53

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 19:15:02

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:15:02

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:21

[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 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:15:02

**US3672333**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'UNBLND_DECIDE'	System	04 Mar 2021 19:15:02

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:21

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:16:58

**US3672333**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:59:21**

[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 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:29:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:59:37

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:21

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:16:58

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:21

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User closed query 'Per CDM, per sponsor review: 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)	14 Apr 2021 08:10:42
Query 'Per CDM, per sponsor review: 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 14:29:31
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 14:29:28
User opened query 'Per CDM, per sponsor review: 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 09:36:09
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:59:37

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:21

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:16:58

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:21

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:16:58

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:21

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:16:58

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:21

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Not Administered (NA)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:16:58

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:21

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:16:58

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:21

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered '1'	System	04 Mar 2021 19:16:58

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:59:21

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'I'	System	04 Mar 2021 19:16:58

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered empty.	System	04 Mar 2021 19:17:24
DataPoint set to visible.	System	04 Mar 2021 19:16:58

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered empty.	System	04 Mar 2021 19:17:24
DataPoint set to visible.	System	04 Mar 2021 19:16:58

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Mar 2021 19:18:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Mar 2021 19:18:03
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:18:03
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 19:17:24
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:18:03
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '12:33' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:18:03
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:17:24

**US3672333**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered '12 Feb 2021 12:33'	System	04 Mar 2021 19:18:03
User entered empty.	System	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '98.5' F reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:18:03
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Mar 2021 19:18:10
Query 'Data is required. Please provide.' answered by System	System	04 Mar 2021 19:18:10
data change (Site from System).		
User entered 'Oral (Oral)' reason for change: Data	(b) (4), (b) (6)	04 Mar 2021 19:18:10
Entry Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Mar 2021 19:18:03
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '77' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:18:03
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'bpm'	System	04 Mar 2021 19:18:03
User entered empty.	System	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:18:03
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'breaths/min'	System	04 Mar 2021 19:18:03
User entered empty.	System	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '106' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:18:03
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'mmHg'	System	04 Mar 2021 19:18:03
User entered empty.	System	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '72' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:18:03
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:17:24

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'mmHg'	System	04 Mar 2021 19:18:03
User entered empty.	System	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:59:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered empty.	System	04 Mar 2021 19:17:24
DataPoint set to visible.	System	04 Mar 2021 19:16:58

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Mar 2021 19:19:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Mar 2021 19:19:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:19:04
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 19:17:24
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:17:24

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:19:04
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '13:41' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:19:04
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered '12 Feb 2021 13:41'	System	04 Mar 2021 19:19:04
User entered empty.	System	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '98.6' F reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:19:04
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:19:04
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '86' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:19:04
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'bpm'	System	04 Mar 2021 19:19:04
User entered empty.	System	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:19:04
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'breaths/min'	System	04 Mar 2021 19:19:04
User entered empty.	System	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '116' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:19:04
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'mmHg'	System	04 Mar 2021 19:19:04
User entered empty.	System	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '77' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:19:04
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'mmHg'	System	04 Mar 2021 19:19:04
User entered empty.	System	04 Mar 2021 19:17:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:19:32

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:19:32

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:21

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 19:20:31

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:21

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:20:31

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:21

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Urine (URINE)'	(b) (4), (b) (6)	04 Mar 2021 19:20:31

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:21

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:20:31

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:21

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 19:20:31

**US3672333**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:20:31

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:21

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '12:55'	(b) (4), (b) (6)	04 Mar 2021 19:20:31

**US3672333**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered '12 Feb 2021 12:55'	System	04 Mar 2021 19:20:31

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 19:21:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:21:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

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 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:21:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'mRNA-1273'	System	04 Mar 2021 19:21:24
DataPoint set to visible.	System	04 Mar 2021 19:16:58

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:21:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '13:10'	(b) (4), (b) (6)	04 Mar 2021 19:21:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered '12 Feb 2021 13:10'	System	04 Mar 2021 19:21:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:21:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'ONCE'	System	04 Mar 2021 19:21:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'INTRAMUSCULAR'	System	04 Mar 2021 19:21:24

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:21:42

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User closed query 'Per GCL Lab Reconciliation: Sample dated 12Feb2021 is recorded under Visit OL-1 visit in EDC, however sample appears to be missing in vendor. Please reconcile the correct date and update if applicable. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 21:21:10
Query 'Per GCL Lab Reconciliation: Sample dated 12Feb2021 is recorded under Visit OL-1 visit in EDC, however sample appears to be missing in vendor. Please reconcile the correct date and update if applicable. ' answered with 'listed in preclarus portal' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 12:18:19
User opened query 'Per GCL Lab Reconciliation: Sample dated 12Feb2021 is recorded under Visit OL-1 visit in EDC, however sample appears to be missing in vendor. Please reconcile the correct date and update if applicable. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 03:24:00
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '12 Feb 2021'	(b) (4), (b) (6)	04 Mar 2021 19:21:42

**US3672333**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:59:21**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '12:53'	(b) (4), (b) (6)	04 Mar 2021 19:21:42

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered '12 Feb 2021 12:53'	System	04 Mar 2021 19:21:42

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:22:16

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:59:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User closed query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	(b) (4) System	04 Mar 2021 19:22:27
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:22:27
User opened query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	System	04 Mar 2021 19:22:16
User entered '2 Feb 2021'	(b) (4), (b) (6)	04 Mar 2021 19:22:16

**US3672333**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:59:21**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '12:22'	(b) (4), (b) (6)	04 Mar 2021 19:22:16

**US3672333**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:59:21**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered '12 Feb 2021 12:22'	System	04 Mar 2021 19:22:27
User entered '2 Feb 2021 12:22'	System	04 Mar 2021 19:22:16

US3672333

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 19:22:35

**US3672333**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:14
User entered 'I'	System	04 Mar 2021 19:22:35

**US3672333**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:49:54
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 19:22:46

US3672333

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:49:54
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 19:22:46

US3672333

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:49:54
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Mar 2021 19:22:46

**US3672333**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:49:54
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 19:22:46

US3672333

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:49:54
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 19:22:50

**US3672333**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:49:54
User entered 'I'	System	04 Mar 2021 19:22:50

**US3672333**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:21**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:49:54
User entered '1'	System	04 Mar 2021 19:22:50
DataPoint set to visible.	System	04 Mar 2021 19:22:50

**US3672333**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:04:56

**US3672333**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:04:56

US3672333

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:59:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:04:56

**US3672333**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User entered 'OLD29'	System	12 Mar 2021 21:04:56

US3672333

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	12 Mar 2021 21:07:19

US3672333

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User closed query 'Visit 4 Day 209 and Visit OL-D57 are both dated 12Mar2021. However, the data on the Vital Signs in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Apr 2021 07:01:03
Query 'Visit 4 Day 209 and Visit OL-D57 are both dated 12Mar2021. However, the data on the Vital Signs in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' answered with 'reconciled' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 16:56:35
User opened query 'Visit 4 Day 209 and Visit OL-D57 are both dated 12Mar2021. However, the data on the Vital Signs in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 00:25:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 21:07:19

US3672333

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:19

**US3672333**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:59:21**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '13:54'	(b) (4), (b) (6)	12 Mar 2021 21:07:19

**US3672333**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User entered '12 Mar 2021 13:54'	System	12 Mar 2021 21:07:19

US3672333

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '98.8' F	(b) (4), (b) (6)	12 Mar 2021 21:07:19

US3672333

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:19

**US3672333**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:59:21**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:19

US3672333

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '94'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:19

**US3672333**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User entered 'bpm'	System	12 Mar 2021 21:07:19

US3672333

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '16'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:19

**US3672333**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User entered 'breaths/min'	System	12 Mar 2021 21:07:19

US3672333

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '116'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:19

**US3672333**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User entered 'mmHg'	System	12 Mar 2021 21:07:19

**US3672333**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '73'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:19

US3672333

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:59:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User entered 'mmHg'	System	12 Mar 2021 21:07:19

**US3672333**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Mar 2021 21:07:19

US3672333

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:19

US3672333

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:19

**US3672333**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:59:21**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '14:59'	(b) (4), (b) (6)	12 Mar 2021 21:07:19

**US3672333**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User entered '12 Mar 2021 14:59'	System	12 Mar 2021 21:07:19

US3672333

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '98.1' F	(b) (4), (b) (6)	12 Mar 2021 21:07:19

US3672333

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:19

**US3672333**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:59:21**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:19

US3672333

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '64'	(b) (4), (b) (6)	12 Mar 2021 21:07:19

**US3672333**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User entered 'bpm'	System	12 Mar 2021 21:07:19

US3672333

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '16'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:19

US3672333

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User entered 'breaths/min'	System	12 Mar 2021 21:07:19

US3672333

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:59:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '94'	(b) (4), (b) (6)	12 Mar 2021 21:07:19

**US3672333**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User entered 'mmHg'	System	12 Mar 2021 21:07:19

**US3672333**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '74'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:19

**US3672333**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User entered 'mmHg'	System	12 Mar 2021 21:07:19

US3672333

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User closed query 'Visit 4 Day 209 and Visit OL-D57 are both dated 12Mar2021. However, the data on the Physical Examination in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:48:54
Query 'Visit 4 Day 209 and Visit OL-D57 are both dated 12Mar2021. However, the data on the Physical Examination in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 16:15:42
User opened query 'Visit 4 Day 209 and Visit OL-D57 are both dated 12Mar2021. However, the data on the Physical Examination in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 00:26:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 21:07:31

US3672333

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:31

**US3672333**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:40

**US3672333**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:40

**US3672333**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:40

**US3672333**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:40

US3672333

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:21

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User closed query 'Per CDM: Please record "YES/NO" response to "Was FSH sample collected" field. If FSH "Yes" collection date and time should be recorded whereas if FSH indicated as "No" Date and Time should be blank. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 12:36:42
Query 'Per CDM: Please record "YES/NO" response to "Was FSH sample collected" field. If FSH "Yes" collection date and time should be recorded whereas if FSH indicated as "No" Date and Time should be blank. Please update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 16:22:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 16:22:07
User opened query 'Per CDM: Please record "YES/NO" response to "Was FSH sample collected" field. If FSH "Yes" collection date and time should be recorded whereas if FSH indicated as "No" Date and Time should be blank. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 09:56:54
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:07:40

**US3672333**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:07:40

**US3672333**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:40

**US3672333**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User entered empty.	System	12 Mar 2021 21:07:40

**US3672333**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:59:21**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:55

**US3672333**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:59:21**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:55

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 21:07:55

US3672333

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User entered 'mRNA-1273'	System	12 Mar 2021 21:07:55
DataPoint set to visible.	System	04 Mar 2021 19:22:50

US3672333

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:55

US3672333

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '14:25'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:55

**US3672333**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:59:21**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User entered '12 Mar 2021 14:25'	System	12 Mar 2021 21:07:55

US3672333

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:07:55

US3672333

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User entered 'ONCE'	System	12 Mar 2021 21:07:55

US3672333

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:59:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User entered 'INTRAMUSCULAR'	System	12 Mar 2021 21:07:55

**US3672333**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:21**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:08:02

**US3672333**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:05:32
User entered 'I'	System	12 Mar 2021 21:08:02

**US3672333**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:41
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 16:54:29

**US3672333**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:41
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:54:29

US3672333

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:59:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:41
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:54:29

**US3672333**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:59:21**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:41
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 16:54:29

US3672333

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:41
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 16:54:33

**US3672333**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:59:21**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:41
User entered 'I'	System	01 Apr 2021 16:54:33

**US3672333**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:04:53

**US3672333**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:04:53

**US3672333**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:04:53

**US3672333**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:59:21**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	21 Apr 2021 22:04:53

US3672333

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4) System	21 Apr 2021 22:05:25
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	21 Apr 2021 22:05:08
User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	21 Apr 2021 22:05:08

US3672333

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:05:25
User entered '21 Apr 2021'	(b) (4), (b) (6)	21 Apr 2021 22:05:08

**US3672333**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:05:08

**US3672333**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 22:05:08

US3672333

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:05:08

**US3672333**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:05:08

**US3672333**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:05:08

US3672333

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:05:08

**US3672333**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 22:05:08

US3672333

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:05:08

**US3672333**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 22:05:08

**US3672333**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:05:08

**US3672333**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 22:05:08

**US3672333**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:05:08

**US3672333**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 22:05:08

US3672333

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:59:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:05:30

**US3672333**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:59:21**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:05:30

**US3672333**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:59:21**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:08:45

US3672333

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:08:45

**US3672333**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:59:21**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:04
User entered '12:55'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:08:45

**US3672333**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:59:21**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '21 Apr 2021 12:55'	System	21 Apr 2021 22:08:45

US3672333

Folder: **Unscheduled 30 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:59:21**

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 15:38:34
User entered '23 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 14:16:23

**US3672333**

**Folder: Unscheduled 30 Sep 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 11 Aug 2021 22:59:21**

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 14:16:23

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:59:21

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'I'	(b) (4), (b) (6)	25 Sep 2020 14:16:23

US3672333

Folder: **Unscheduled 30 Sep 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:59:21**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'I'	(b) (4), (b) (6)	25 Sep 2020 14:16:23

**US3672333**

**Folder: Unscheduled 30 Sep 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 11 Aug 2021 22:59:21**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'I'	(b) (4), (b) (6)	25 Sep 2020 14:16:23

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 15:38:50
User entered '23 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 14:17:03

**US3672333**

**Folder: Unscheduled 30 Sep 2020**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '15:15'	(b) (4), (b) (6)	25 Sep 2020 14:17:03

**US3672333**

**Folder: Unscheduled 30 Sep 2020**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:05
User entered '30 Sep 2020 15:15'	System	26 Oct 2020 15:38:50
User entered '23 Sep 2020 15:15'	System	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '98.4' F	(b) (4), (b) (6)	25 Sep 2020 14:17:03

**US3672333**

**Folder: Unscheduled 30 Sep 2020**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Oral (Oral)'	(b) (4), (b) (6)	25 Sep 2020 14:17:03

**US3672333**

**Folder: Unscheduled 30 Sep 2020**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 14:17:03

**US3672333**

**Folder: Unscheduled 30 Sep 2020**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '78'	(b) (4), (b) (6)	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:05
User entered 'bpm'	System	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '17'	(b) (4), (b) (6)	25 Sep 2020 14:17:03

**US3672333**

**Folder: Unscheduled 30 Sep 2020**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:05
User entered 'breaths/min'	System	25 Sep 2020 14:17:03

**US3672333**

**Folder: Unscheduled 30 Sep 2020**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '137'	(b) (4), (b) (6)	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:05
User entered 'mmHg'	System	25 Sep 2020 14:17:03

**US3672333**

**Folder: Unscheduled 30 Sep 2020**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '89'	(b) (4), (b) (6)	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:05
User entered 'mmHg'	System	25 Sep 2020 14:17:03

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:59:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:05

**US3672333**

**Folder: Unscheduled 30 Sep 2020**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:59:21**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:05

**US3672333**

**Folder: Unscheduled 30 Sep 2020**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:04:58
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 14:17:20

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:21

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:04:58
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User closed query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	26 Oct 2020 15:38:57
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 15:38:57
User opened query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	26 Oct 2020 15:38:34
User entered '23 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 14:17:20

**US3672333**

**Folder: Unscheduled 30 Sep 2020**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:04:58
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Urine (URINE)'	(b) (4), (b) (6)	25 Sep 2020 14:17:20

**US3672333**

**Folder: Unscheduled 30 Sep 2020**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:04:58
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	25 Sep 2020 14:17:20

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:59:21

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:04:58
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 14:17:20

**US3672333**

**Folder: Unscheduled 30 Sep 2020**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:04:58
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 14:17:20

**US3672333**

**Folder: Unscheduled 30 Sep 2020**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:04:58
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 14:17:20

**US3672333**

**Folder: Unscheduled 30 Sep 2020**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:59:21**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:04:58
User entered empty.	System	25 Sep 2020 14:17:20

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:04:54
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Unscheduled on 30Sep2020. Please clarify and update if appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 02:17:33
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Unscheduled on 30Sep2020. Please clarify and update if appropriate.' answered with 'listed in preclarus portal' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 12:25:29
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Unscheduled on 30Sep2020. Please clarify and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:55:16
User closed query 'Per GCL Lab Recon: GCL received a sample for Immunogenicity assessment for V2D29 dated 23 SEP 2020, however this date matches an unscheduled visit in EDC. please confirm the V2D29 immunogenicity sample belongs to the unscheduled EDC visit.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 15:46:54
Query 'Per GCL Lab Recon: GCL received a sample for Immunogenicity assessment for V2D29 dated 23 SEP 2020, however this date matches an unscheduled visit in EDC. please confirm the V2D29 immunogenicity sample belongs to the unscheduled EDC visit.' answered with 'date of illness visit corrected' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 15:39:10
User opened query 'Per GCL Lab Recon: GCL received a sample for Immunogenicity assessment for V2D29 dated 23 SEP 2020, however this date matches an unscheduled visit in EDC. please confirm the V2D29 immunogenicity sample belongs to the unscheduled EDC visit.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:44:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 14:17:48

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:04:54
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	26 Oct 2020 15:38:34
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	26 Oct 2020 15:38:25
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 15:38:25
User entered '23 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 14:17:48

US3672333

Folder: Unscheduled 30 Sep 2020

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:59:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:04:54
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:30:01
User entered '15:35'	(b) (4), (b) (6)	25 Sep 2020 14:17:48

**US3672333**

**Folder: Unscheduled 30 Sep 2020**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:59:21**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:04:54
User entered '30 Sep 2020 15:35'	System	26 Oct 2020 15:38:25
User entered '23 Sep 2020 15:35'	System	25 Sep 2020 14:17:48

US3672333

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:59:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:38:42

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User closed query 'User opened query 'Per DM CLR: RQ: Response noted, however, please provide if it is Ipsilateral (Same side) or Contralateral (Opposite) of the Vaccine site. Update as appropriate.' (Site from DM).' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 04:47:27
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 axillary - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Dec 2020 20:36:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Dec 2020 20:36:45
Data point term sent to Coder	System	17 Dec 2020 19:57:25
Query 'User opened query 'Per DM CLR: RQ: Response noted, however, please provide if it is Ipsilateral (Same side) or Contralateral (Opposite) of the Vaccine site. Update as appropriate.' (Site from DM).' answered with 'reconciled' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 19:57:25
Coding entries removed.	(b) (4), (b) (6)	17 Dec 2020 19:57:13
User entered 'LYMPHADENOPATHY R UNDERARM (opposite)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 19:57:13
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' canceled (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 05:44:58
User opened query 'User opened query 'Per DM CLR: RQ: Response noted, however, please provide if it is Ipsilateral (Same side) or Contralateral (Opposite) of the Vaccine site. Update as appropriate.' (Site from DM).' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 05:44:44
Query 'Per DM CLR: RQ: Response noted, however, please provide if it is Ipsilateral (Same side) or Contralateral (Opposite) of the Vaccine site. Update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 05:43:50
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 05:43:46

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:21

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: RQ: Response noted, however, please provide if it is Ipsilateral (Same side) or Contralateral (Opposite) of the Vaccine site. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 15:02:03
User closed query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:10:32
Query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, clarify.' answered with 'PLEASE READ THE TERM FOR THE ADVERSE EVENT AS IT CLEARLY NOTES THE LATERALITY' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 00:13:51
User opened query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 00:07:05
User closed query 'Per DM CLR: Please review and update AE term to reflect specific body location of LYMPHADENOPHTHY. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:21:25
Query 'Per DM CLR: Please review and update AE term to reflect specific body location of LYMPHADENOPHTHY. Please reconcile with the ConMed eCRF so there is an appropriate match. ' answered with 'Updated per query.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 20:28:07
User coded data point as SOC: Blood and lymphatic system disorders, HLG: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:43:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:43:35
Data point term sent to Coder	System	21 Oct 2020 13:30:31

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:21

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	(b) (4), (b) (6)	21 Oct 2020 13:29:36
User entered 'LYMPHADENOPATHY R Underarm' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 13:29:36
User opened query 'Per DM CLR: Please review and update AE term to reflect specific body location of LYMPHADENOPATHY. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:37:15
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 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 17:41:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 17:41:50
Data point term sent to Coder	System	14 Sep 2020 17:40:52
User entered 'LYMPHADENOPATHY'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User closed query 'Per DM CLR - RQ: Site's response noted. However, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:47:44
Query 'Per DM CLR - RQ: Site's response noted. However, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 00:17:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:17:39
User opened query 'Per DM CLR - RQ: Site's response noted. However, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 00:08:05
User closed query 'Per DM CLR: Please confirm if this pertains to Underarm gland swelling. If yes. note that solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started at after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:24:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please confirm if this pertains to Underarm gland swelling. If yes, note that solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started at after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' answered with 'Event took place greater than 7 days after an injection' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 15:33:08
User opened query 'Per DM CLR: Please confirm if this pertains to Underarm gland swelling. If yes, note that solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started at after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:37:21
User entered 'Yes (Y)'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '7 Sep 2020'	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39
	(b) (4)	

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered empty.	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39
	(b) (4)	

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:59:21**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 17:40:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User closed query 'Per DM CLR: RQ: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 07:16:02
Query 'Per DM CLR: RQ: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 12:15:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 12:15:42
User opened query 'Per DM CLR: RQ: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 10:27:38
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 16:22:46
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'still ongoing ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 20:07:30
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 01:13:43
User entered 'Yes (Y)'	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '18 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:15:42
User entered empty.	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:59:21**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered empty.	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39
	(b) (4)	

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:59:21**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 17:40:39

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '0'	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39
	(b) (4)	

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '0'	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '0'	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered empty.	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39
	(b) (4)	

US3672333

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered empty.	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39
	(b) (4)	

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered empty.	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered empty.	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '0'	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '0'	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '0'	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
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	14 Sep 2020 17:41:06
User entered 'Related (RELATED)' reason for change: Data Entry Error	System	14 Sep 2020 17:41:06
User opened query 'Data is required. Please complete.' (Site from System).	Patty Howenstine (b) (4)	14 Sep 2020 17:41:06
User entered empty.	(b) (4)	
	System	14 Sep 2020 17:40:39
	Patty Howenstine (b) (4)	14 Sep 2020 17:40:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
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	14 Sep 2020 17:41:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	14 Sep 2020 17:41:06
User opened query 'Data is required. Please complete.' (Site from System).	Patty Howenstine (b) (4)	14 Sep 2020 17:41:06
User entered empty.	(b) (4)	
	System	14 Sep 2020 17:40:39
	Patty Howenstine (b) (4)	14 Sep 2020 17:40:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
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	14 Sep 2020 17:41:06
User entered 'None (NONE)' reason for change: Data Entry Error	System	14 Sep 2020 17:41:06
User opened query 'Data is required. Please complete.' (Site from System).	Patty Howenstine (b) (4)	14 Sep 2020 17:41:06
User entered empty.	(b) (4)	
	System	14 Sep 2020 17:40:39
	Patty Howenstine (b) (4)	14 Sep 2020 17:40:39
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:59:21**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '1'	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '0'	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '0'	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:21

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 12:15:42
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 17:41:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 17:41:06
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:41:06
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 17:40:39
User entered empty.	Patty Howenstine (b) (4) (b) (4)	14 Sep 2020 17:40:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:59:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered empty.	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered empty.	(b) (4) Patty Howenstine (b) (4)	14 Sep 2020 17:40:39
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 17:40:39

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 17:40:39

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 07:44:46
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'Subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 20:22:19
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 20:20:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 20:20:56
Data point term sent to Coder	System	24 Nov 2020 20:19:35
Coding entries removed.	(b) (4), (b) (6)	24 Nov 2020 20:18:56
User entered 'UPPER RESPIRATORY INFECTION (URI)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:18:56
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 12:55:07
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 15:24:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 15:24:37
Data point term sent to Coder	System	14 Oct 2020 15:02:19
User entered 'Upper Respiratory Infection URI'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '24 Sep 2020'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:01:35

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User entered empty.	System	14 Oct 2020 15:01:35

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

**If not Ongoing, end date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '30 Sep 2020'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:01:35

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User entered empty.	System	14 Oct 2020 15:01:35

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:01:35

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:01:35

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:01:35

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:01:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:21

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User closed query 'Per CDM: Site reported as study treatment was not given due to "NO SWAB RESULT FOUND FROM DAY 1" per day 29 Exposure form. So please reconcile the response for "Action taken with investigational product" and update accordingly.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 05:49:32
Query 'Per CDM: Site reported as study treatment was not given due to "NO SWAB RESULT FOUND FROM DAY 1" per day 29 Exposure form. So please reconcile the response for "Action taken with investigational product" and update accordingly.' answered with 'we could have retested. This was primary reason per PI' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 12:16:46
User opened query 'Per CDM: Site reported as study treatment was not given due to "NO SWAB RESULT FOUND FROM DAY 1" per day 29 Exposure form. So please reconcile the response for "Action taken with investigational product" and update accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 08:32:11
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		24 Nov 2020 20:21:16
Query 'Action Taken with Investigational Product is System Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).		24 Nov 2020 20:21:16
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	18 Nov 2020 21:15:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:21

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: The reason provided for study treatment not given on Exposure (V2D29) page is 'NO SWAB RESULT FOUND FROM DAY 1' However, 'Delayed' is recorded here. Please confirm the next dose of IP is given or not and update the respective forms accordingly or else provide clarification. Thank you. ' (Site from DM). Query 'Per CDM: The reason provided for study treatment not given on Exposure (V2D29) page is 'NO SWAB RESULT FOUND FROM DAY 1' However, 'Delayed' is recorded here. Please confirm the next dose of IP is given or not and update the respective forms accordingly or else provide clarification. Thank you. ' answered with 'subject was never given the second dosage' (Site from DM). User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 23:47:46
User opened query 'Per CDM: The reason provided for study treatment not given on Exposure (V2D29) page is 'NO SWAB RESULT FOUND FROM DAY 1' However, 'Delayed' is recorded here. Please confirm the next dose of IP is given or not and update the respective forms accordingly or else provide clarification. Thank you. ' (Site from DM). User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4), (b) (6)	26 Oct 2020 15:35:27
	(b) (4), (b) (6)	26 Oct 2020 15:35:09
	(b) (4), (b) (6)	26 Oct 2020 05:40:46
	(b) (4), (b) (6)	14 Oct 2020 15:01:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	21 Oct 2020 13:35:01
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 13:35:01
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	14 Oct 2020 15:01:35
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 13:35:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 13:35:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	21 Oct 2020 13:35:01
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 15:01:35
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:21

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 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:01:35

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:30:26
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User entered '0'	System	14 Oct 2020 15:01:35

**US3672333**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50
User entered '0'	System	14 Oct 2020 15:01:35

US3672333

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:59:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:47:50

US3672333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 11 Aug 2021 22:59:21**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:10:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:41:37

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: ETONOGESTREL, PRODUCTSYNONYM: NEXPLANON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 13:38:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 13:38:38
Data point term sent to Coder	System	21 Oct 2020 13:37:39
Coding entries removed.	(b) (4), (b) (6)	21 Oct 2020 13:37:24
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: ETONOGESTREL, PRODUCTSYNONYM: NEXPLANON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 18:43:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 18:43:51
Data point term sent to Coder	System	28 Aug 2020 18:43:07
User entered 'Nexplanon'	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
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) (4), (b) (6)	19 Mar 2021 07:17:04
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)	18 Mar 2021 12:17:23
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 12:17:17
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)	04 Jan 2021 17:42:15
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered 'Contraception'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User closed query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please verify if the number of implant is a more appropriate recording. Please review and correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:25:02
Query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please verify if the number of implant is a more appropriate recording. Please review and correct the dosage or provide explanation for alternate dosage.' answered with 'Updated dosage' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 13:49:36
User entered '68' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 13:49:27
User opened query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please verify if the number of implant is a more appropriate recording. Please review and correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 23:30:23
User entered '40'	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 13:49:27
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 13:36:07
User entered 'ug (ug)'	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered empty; reason for change Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 13:49:27
User entered 'mcg' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 13:36:07
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:25:37
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'Updated per query.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 20:26:56
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 20:26:46
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 23:30:39
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered 'Every 3 years' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 20:26:46
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:42:25
	(b) (4), (b) (6)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "SUBDERMAL" is a more appropriate recording. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:25:32
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "SUBDERMAL" is a more appropriate recording. Please update route as appropriate.' answered with 'Subdermal updated.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 13:38:22
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 13:37:24
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Verify if "SUBDERMAL" is a more appropriate recording. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 23:30:31
User entered 'Transdermal (TRANSDERMAL)'	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:59:21**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
	(b) (4)	
User entered 'Subdermal' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 13:37:24
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered '26 Nov 2018'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:59:21**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:42:25

US3672333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 18:42:25

**US3672333**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 20:26:46
User entered '1'	System	28 Aug 2020 18:42:25

US3672333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 20:26:46
User entered '1'	System	28 Aug 2020 18:42:25

**US3672333**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:59:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 20:26:46
User entered '804 (804)'	System	28 Aug 2020 18:42:25

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:45:49
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
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)	19 Nov 2020 20:34:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 20:34:04
Data point term sent to Coder	System	19 Nov 2020 20:32:41
User entered 'influenza vaccine'	(b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:45:49
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:45:49
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered 'influenza prophylaxis'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:45:49
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:45:49
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:45:49
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered 'injection'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:45:49
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:45:49
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:45:49
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:45:49
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:45:49
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered '9 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:45:49
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:32:15

**US3672333**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:45:49
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:45:49
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered '9 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:45:49
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:32:15

US3672333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:45:49
User entered empty.	System	19 Nov 2020 20:32:15

US3672333

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:45:49
User entered empty.	System	19 Nov 2020 20:32:15

**US3672333**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:59:21**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:45:49
User entered empty.	System	19 Nov 2020 20:32:15

US3672333

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:59:21**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:47:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:07:55

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**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 11 Aug 2021 22:59:21**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:10
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:37:00

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:59:21

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:10
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:21:16
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 21:15:36
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4), (b) (6)	26 Oct 2020 15:37:00

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:59:21

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:10
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:19:44
User closed query 'Per CDM: Other, specify indicates AE#1. However, AE#2 indicates Action taken with investigational product as ' Investigational Product Withdrawn' Please confirm AE# again and record correct AE record number instead of details. Thank you' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:36:49
Query 'Per CDM: Other, specify indicates AE#1. However, AE#2 indicates Action taken with investigational product as ' Investigational Product Withdrawn' Please confirm AE# again and record correct AE record number instead of details. Thank you' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 18:16:21
User entered 'AE#2' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 18:16:14
User opened query 'Per CDM: Other, specify indicates AE#1. However, AE#2 indicates Action taken with investigational product as ' Investigational Product Withdrawn' Please confirm AE# again and record correct AE record number instead of details. Thank you' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 14:40:16
User entered 'AE#1 and dosing discontinued due to day 1 swab never found.' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:21:39
User closed query 'Per CDM: Primary reason for dosing discontinuation is 'AE ' However, specification is not matching with the Primary reason. Per CCG pg.42 If reason for discontinuation is 'Adverse Event, SAE, Physician Decision, Withdrawal of Consent, Protocol Deviation or Other Please consider to the Specify reason. Please confirm and update appropriately. Else clarify Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 16:24:26

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:59:21

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Query 'Per CDM: Primary reason for dosing discontinuation is 'AE ' However, specification is not matching with the Primary reason. Per CCG pg.42 If reason for discontinuation is 'Adverse Event, SAE, Physician Decision, Withdrawal of Consent, Protocol Deviation or Other Please consider to the Specify reason. Please confirm and update appropriately. Else clarify Thank you.' answered with 'updated to OTHER' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 21:15:44
User opened query 'Per CDM: Primary reason for dosing discontinuation is 'AE ' However, specification is not matching with the Primary reason. Per CCG pg.42 If reason for discontinuation is 'Adverse Event, SAE, Physician Decision, Withdrawal of Consent, Protocol Deviation or Other Please consider to the Specify reason. Please confirm and update appropriately. Else clarify Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 08:46:55
User entered 'no second dosage given due to no day 1 swab found'	(b) (4), (b) (6)	26 Oct 2020 15:37:00